EXHIBIT C

8-12-19 ROUGH DRAFT OF DEPOSITION OF RICHARD WASSERMAN, M.D.

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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO WAVE 11 CASES	

Monday, August 12, 2019

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DEPOSITION OF RICHARD M. WASSERMAN, M.D., held at Greenberg Traurig, 10845 Griffith Peak Drive, Suite 600 Las Vegas, Nevada, commencing at 9:31 a.m., on the above date, before Janet C. Trimmer, NV CCR 864.

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A P P E A R A N C E S

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On behalf of the Defendants:

BOWMAN AND BROOKE LLP
BY BARRY J. KOOPMANN, ESQ.

I N D E X

E X H I B I T S

NUMBER	PAGE	DESCRIPTION
Exhibit 1	7	"Notice to Take Deposition of Richard M. Wasserman, M.D. FACOG"
Exhibit 2	10	"Richard Wasserman, MD, FACOG, FPMRS, General Report Regarding TVT, TVT-EXACT, TVT-Obturator, and TVT-Abbrevo Mid-Urethral Slings"
Exhibit 3	10	Curriculum Vitae of Richard M. Wasserman, MD FACOG
Exhibit 4	10	"Richard Wasserman, General Materials List, in Addition to Materials Referenced in Report"
Exhibit 5	10	"Richard Wasserman, Supplemental General Materials List, in Addition to Materials Referenced in Report"
Exhibit 6	11	Dr. Richard Wasserman PC, Invoice, dated 1-3-2019
Exhibit 7	11	Compilation of e-mails
Exhibit 8	11	Letter dated 12-1-18 from Jeffrey L. Clemons, MD, to Attorney General of Washington

EXHIBITS (CONTINUED):

NUMBER	PAGE	DESCRIPTION
Exhibit 9	11	Flash drive (retained by counsel)

INFORMATION TO BE PROVIDED

08-12-19 Wasserman MD Rough Draft_TVT_Exact_TVT-O, Abbrevo.txt

Page	Line
20	19
23	19

Las Vegas, Nevada; Monday, August 12, 2019

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Whereupon --

(In an off-the-record discussion held prior to the commencement of the proceedings, counsel agreed to waive the court reporter's requirements under Rule

30(b)(5)(A) of the Federal Rules of Civil Procedure.)

RICHARD M. WASSERMAN, M.D.

having been first duly sworn to testify to the truth, was examined and testified as follows:

EXAMINATION

BY MR. FAES:

Q. Good morning, Dr. Wasserman. Could you state your full name for the record, please?

A. Richard ^ mark Wasserman.

Q. You have been hired as a general liability expert for Ethicon in this litigation; is that correct?

A. Yes.

Q. And you produced an expert report that's dated March 21st of 2019; is that correct?

A. That's correct.

Q. And the products you have written a report on are the TVT, TVT-Exact, TVT-Obturator, and TVT-Abbrevo devices; is that right?

A. That's correct.

Q. Before I get too far, other than the flash drive -- well, let me back up.

(Exhibit 1 was marked for identification.)

BY MR. FAES:

Q. Doctor, I'm going to mark what's been marked as Exhibit Number 1 to your deposition, and this is the notice of your deposition here today. Have you seen that document before?

A. Yes, I have.

Q. In the document starting on page 6, there's a schedule A that asks that you bring various documents and items to the deposition here with you today.

A. Yes.

Q. Have you seen that list before today?

A. I have. I'm trying to find it though -- right here, yes, got it.

Q. Have you brought any documents with you here today in response to that notice?

A. Yes, I have.

Q. What have you brought?

A. I have my CV. In regards to flash drives, Barry has those. Any documents reviewed -- this is my review documents that are here (indicating). Any medical records, medical bills unpublished, I don't have any of those. Any depositions pending other records, court -- I don't have any of that. Any Ethicon products, I don't have any products. Any documents including time sheets, invoices. I have an invoice for you for preparation. Okay. Here you go. (Handed.).

Any communications, I believe Barry should

have those communications; right here (indicating).

(Handed.)

Q. Any and all documents including consulting agreements, that should all be in there in that packet.

It's number 9. I have not been a consultant for Ethicon regarding cadaver labs or teaching or anything like that.

My tax records, I do not have my tax records?

MR. KOOPMANN: For the record, we objected to that one, number 10, the copies of schedule C and form 1099.

MR. FAES: So noted.

THE WITNESS: Correspondence, you should have

all of that, between me and Ethicon.

I haven't had any direct correspondence with Ethicon for e-mails, I don't have anything in my possession.

Consulting agreements for work as a consultant. The only work I've done as a consultant for Ethicon has been on these cases.

I don't have any PowerPoints or video presentations. I don't have that (indicating).

So in regards to any number 16, any and all documents including transcripts or statements between you and any governmental agency regarding female mesh products," in December of last year I used to practice

in Seattle, Washington, and while I was there, there was an attorney general case and I did sign a letter regarding midurethral slings, and I have a copy of that for you.

Q. Okay. I'm going to definitely have some questions about that. So do you have a copy of that letter?

A. Yeah. Here you go (handed.

So I did not write that, but I'm a signatory on it.

Q. Mind if I staple this? I just want to keep it together.

A. And 17 and 18 --

Q. Are you finished?

A. And 17 and 18, that's it.

Q. So just for housekeeping, I'm going to mark as Exhibit 2, make sure I don't give you my highlighted copy, your expert report.

(Exhibit 2 was marked for identification.)

BY MR. FAES:

Q. I'm going to mark as Exhibit 3 your CV that was produced with your report.

(Exhibit 3 was marked for identification.)

BY MR. FAES:

Q. I'm going to mark as Exhibit Number 4 your original reliance list that was served with your report.

(Exhibit 4 was marked for identification.)

Q. I'm going to mark as Exhibit 5 your supplemental reliance list.

(Exhibit 5 was marked for identification.)

BY MR. FAES:

Q. I'm going to mark as Exhibit Number 6, and I'm going to hold onto it for just the time being because I'm going to ask you some questions about it in a minute, your invoice that's dated January 3rd of 2019 for $400.

(Exhibit 6 was marked for identification.)

BY MR. FAES:

Q. I'm going to mark as Exhibit Number 7 looks like a composite exhibit of e-mails between you and counsel for defendants. Is that an accurate representation of Exhibit Number 7?

A. Yes.

(Exhibit 7 was marked for identification.)

BY MR. FAES:

Q. And I'm going to mark as Exhibit Number 8 the letter to the attorney general of Washington that you signed, and when it's ready I'll mark as Exhibit Number 9 the flash drive that I believe counsel is preparing.

(Exhibit 8 was marked for identification.)

(Exhibit 9 was marked for identification.)

MR. FAES: And I'll probably retain that

flash drive.

MR. KOOPMANN: That's fine.

MR. FAES: Rather than leaving it with the court reporter.

Q. So looking at Exhibit Number 6, it looks like we've only got one copy of it, this is an invoice dated January 3rd of this year; right?

A. You know what? It is dated January 3rd,

however I forgot to update the date actually when it was billed.

Q. So when is the date that this was actually billed?

A. Last week.

Q. Does this represent all of the work that you have done on your expert report for four different products up to this date?

A. That was the work that was done on preparing this report, yes. The reason why -- I'm terrible at billing, and a lot of the secretarial admin work for consulting, and printing up invoices and getting in stuff on time, I'm not all that good. I just kind of do this on the side. So I didn't update the date. I bet you all of the invoices I've sent have that date because it's like the default date, probably when I saved this initially.

Q. Okay. And it looks like, from your Exhibit Number 8 -- I'm sorry -- Exhibit Number 7 that has

some e-mails between you and defense counsel, it looks like the first time that you were contacted to potentially be an expert for Ethicon and Johnson & Johnson was about June of 2018?

A. Correct.

Q. Is that accurate?

A. That is correct. So about a year ago I was asked by Ethicon just to kind of review some cases, so I kind of looked over some cases and brought some reports for those cases.

And then in March or before March when I submitted this report, I was asked to just do a general kind of report for them.

Q. So you have submitted bills for other cases?

A. That is correct.

Q. But is Exhibit Number 6 the sum total of all of the work that you've done on your general expert report other than, you know, the preparation for your deposition here today?

A. Yes. So the work that was done for preparing this report, that's what it's reflective of.

Q. So it only took you 12 hours -- and that includes all the review of materials and drafting?

A. No, no, no, no, no. The review of materials is completely -- so I reviewed these materials ongoing over long periods of time. So the actual review of materials didn't take 12 hours. That took a lot

more hours, but that's just in the course of my clinical practice as well, just keeping up on things and being current and reading. So I don't feel comfortable billing for reading stuff that goes into

preparing this. Because I've done other case-specific ones on chart reviews and so a lot of the material was there, so a lot of the work was put in on previous kind of reports.

Q. Okay.

A. But for this report was just on these four products, I've done a lot of other work on -- that was for other cases and other times.

Q. So if I understand you correctly, you are saying that when you review the general medical literature and things like that for the general report, you don't bill your time for that?

A. That is correct.

Q. What about the -- there's a number of Ethicon depositions that are on your reliance list.

A. Yes.

Q. Did you review all of those --

A. Yes.

Q. -- that are your reliance list?

A. Yes.

Q. And did you bill for that time?

A. No.

Q. Why didn't you bill for that time?

A. You know, I didn't really think that that was part of the billing process. I don't know. Maybe I

should have. But I didn't really feel comfortable in regards to billing Ethicon for me for reading the documents that were provided. I thought that that's just a good idea for me as a clinician to understand and just for background in regards to preparing for the report.

Q. And you reviewed a number of Ethicon internal documents that were sent to you as well; right?

A. Yes.

Q. Did you bill for any of that time reviewing those documents?

A. No, but those documents were provided to me way back last year, so it's been over the course of the past year. So when I got the assignment to just write this general report, I was already kind of up to speed in regards to what I needed to be aware of in order to write the report, so that that 12 hours is just for the -- kind of putting the report together.

Q. Is there any kind of -- did you do any kind of timekeeping to keep track of how much time you spent reviewing either the deposition testimony that you reviewed and relied on for this report or the Ethicon internal documents that you reviewed --

A. I didn't itemize it like that.

MR. KOOPMANN: Just be sure to let him finish

his question and then give the answer.

THE WITNESS: I did not itemize it like that.

BY MR. FAES:

Q. I understand you didn't itemize it like that, but my question is, is there any resource anywhere that I could go to for me to be able to determine how much time you spent reviewing, for instance, the deposition testimony of Ethicon witnesses that you say you have reviewed and relied for this report?

A. There's not.

Q. Same question with regard to Ethicon internal documents?

A. To actually quantify the amount of time I spent on it?

Q. Yes.

A. I'm not able to produce documents that support that.

Q. Okay. Same with regard to the large amount of medical literature that's on your reliance list?

A. No, I did not bill for that. I did not keep a journal for that.

Q. Do you have an estimate of how long it took you to review the deposition testimony?

A. It's over a long period of time, and it was starting and stopping. So I can't quantify the exact

number of minutes for you.

Q. Do you have an estimate of how long it took you to review the Ethicon internal documents that are on your reliance list?

A. Again, same answer in regards to review. I cannot -- I looked at it all but it was start and stop over a long period of time and I did not keep a journal as to how much time was spent on each document.

Q. Have you been hired as an expert witness for any other transvaginal mesh?

A. No, I have not.

Q. -- manufacturers? That was going to be the end of my question. I'm a slow talker.

A. I'm wait. Okay.

Q. Have you been an expert witness for any other transvaginal mesh manufacturers?

A. I have not.

Q. What's your understanding of what you were hired to do on behalf of Ethicon in this litigation?

A. I was asked to provide my opinions regarding midurethral slings.

Q. So your understanding was that you were hired to offer your opinion on the midurethral slings as an entire product class?

A. These four specific products that are in question.

Q. Okay. So is it your understanding that you were asked to offer your opinions on midurethral slings as a class, the TVT, the TVT-O, the Abbrevo, and the Exact specifically, or all of them?

A. It was specifically those four.

Q. Okay. Have you ever been deposed before today?

A. I have been deposed as a treating physician.

Q. So this is your first time being deposed as an expert witness; is that accurate?

A. That is correct.

Q. How many times have you deposed as a treating physician?

A. Probably five or six.

Q. And of those five or six times that you were deposed as a treating physician, were those all transvaginal mesh cases?

A. Yes.

Q. And what were your role in those cases? Were you the implanting physician in all --

A. No.

Q. -- of those cases?

A. No, I was not. Some I was the implanting

physician. Some I was a treating physician. Some I just saw the patient and took care of them

postoperatively.

Q. Okay. And on how many of those cases were you the implanting physician?

A. I would say about half, two or three.

Q. Okay. So in those two to three cases where you were the implanting physician, did the plaintiffs in those cases have a complication following the surgery that they were suing Ethicon and Johnson & Johnson for?

A. They were suing Johnson & Johnson, yes, they were.

Q. Okay. So all -- both of the two to three -- strike that. Both of the two to three cases that you were deposed on where you were the implanting physician, the patient was suing Ethicon and Johnson & Johnson for alleged injuries due to the mesh; correct?

A. That's what they alleged; that is correct.

Q. Anywhere in your materials that were produced, either in your CV or your report, have you produced or prepared a testimonial history, meaning any time that you have been either deposed or testified in court?

A. I don't know what a testimonial history is, so I probably haven't been asked for one.

Q. Okay. So that's what I was trying to explain in my question. Testimonial history is just a list of

every time in the past four to five years that you have either been deposed under oath or given testimony in a court. You've not prepared one of those; right?

A. Testimony actually in a court?

Q. In court or in a deposition.

A. So in court, I have never given testimony in a court. In regards to deposition, it's just those five to six times that I was deposed as a treating physician in the past.

Q. Okay. And you understand that here when you are being deposed, you are sworn to tell the truth and your testimony has the same effect that it would as if you were in a court of law; right?

A. I do.

MR. FAES: We are going to ask that we get a testimonial history from Dr. Wasserman. I'll make a request for that after the deposition?

MR. KOOPMANN: Okay. But I think the Federal Rules require that he provide one or we produce one for him if he's been an expert, and he's testified he's never been an expert before.

MR. FAES: I'm not going to argue on the record. I'm not sure that's what the Rules require.

MR. KOOPMANN: Okay.

MR. FAES: But we will make our request and you can respond to it.

MR. KOOPMANN: Okay.

BY MR. FAES:

Q. How many other cases have you worked on for Ethicon and Johnson & Johnson as an expert witness?

A. So I've worked on probably about a dozen or so, and that's a dozen or so specific cases over that past year period of time.

Q. And when did your litigation cutting work with Ethicon and Johnson & Johnson start? When did you start first having a litigation consulting arrangement with them?

A. Litigation consulting arrangement? So I'm not 100 percent sure what you mean by that. However, that's when that letter of engagement type of a thing was started, was that June of 2018 or July? You mentioned it earlier.

Q. Okay.

A. That's when it started.

Q. My understanding is this is when you first began to be sent general materials. Was that also

when you were first engaged as kind of a case-specific expert to work on the dozen of so cases that you have worked on since approximately June of 2018?

A. Correct. That's when I started working with them and they started sending me some documents, kind of getting me up to speed in regards to the information, and then I started reviewing cases.

Q. And actually, to be clear for the record, I'm

looking further into Exhibit 7. It looks like there's an actual letter here from Bowman and Brooke to you dated March 12, 2018, which appears to be an engagement letter that you signed on March 17th of 2018. Does that sound correct?

A. That sounds correct, so it's a little over a year.

Q. Have you billed for each of those 12 cases?

A. Yes.

Q. But you haven't brought any of those invoices with you here to the deposition today?

A. I was not asked to. I was asked to just bring invoices regarding preparation of this report.

Q. On average, how much would you say that you have billed for each of those dozen or so cases?

A. It depends on the case. So some of them were short. Some of them were long. A lot of them, I

would get the case material and start reviewing it and then the case settled and I was told to stand down on those cases. So those are maybe an hour or two.

And there are other ones that went the full gamut, where I reviewed the entire chart, took notes on the chart, and prepared a report based on the patient's specific history, and those probably took anywhere from 9 to 12 hours, 11 hours per case.

Q. Okay. Is it fair to say, then, that you have been paid at least $50,000 to this point by Ethicon

and Johnson & Johnson for your work as a litigation consultant?

A. No.

Q. Okay. How much have you been paid so far by Ethicon and Johnson & Johnson?

A. Oh, I would say total, everything together up until this point, under $20,000, but I'm just guessing at this point.

MR. FAES: And we are going to make a request that the invoices for all the cases that he's worked on be produced to us. I think that's responsive to the document requests in the notice, but...

Q. Have you ever been an expert witness prior to March of 2018 in litigation for anyone?

A. I have not.

Q. So you've never been -- it's true that you've never been an expert witness for a plaintiff; correct?

A. I've not.

Q. It's fair to say that you have only been an expert witness for a medical device company at this point in time; right?

A. Well, this is the only time I've ever been an expert witness, and I'm an expert witness for a medical device company, so I don't think that it's over a long period of time, because it's only -- the total number is one.

Q. Okay. But my question is, it's true that you

haven't been an expert witness in litigation for anyone other than a medical device company to date; correct?

A. I think I answered the question, but like I said, I've only been -- this is the only time I've ever been an expert witness, and I'm an expert witness for Johnson & Johnson. So...

Q. And the only -- strike that.

And you've been an expert witness for a medical device company on at least a dozen separate occasions; right?

A. I've done chart reviews and written reports. So yes, a dozen or so right around there.

Q. And the number of times that you have served as an expert witness in litigation is zero; right?

A. I've never been asked, so, yes.

Q. Have you ever been sued before?

A. Have I ever been sued? No.

Q. You've never been -- have you ever been accused of medical malpractice?

A. I was named in a suit that settled. So it was my group that I was previously with. There was a case that did settle, and I was one of the physicians that case.

Q. Okay. So it's fair to say that you have been sued at least once; right?

A. I don't think there was ever a lawsuit that

was filed, but I was not a part of that discussion.
Q. Okay. Do you know what the nature of the complaint or allegations being made in that case were?
A. I do. So there was a patient, a number of years back in Seattle, that a Pap smear was performed, and she alleged that she never got the results of her Pap smear and they were abnormal and there was a problem within my group that letters and contact never got made and the -- they -- that was my phone. I'll sorry. I'll turn the ringer on.
Q. It's a good thing we're not on video.

A. And they threatened to have a lawsuit and my group just went to them and they settled it before a lawsuit was filed, but it was reportable.
Q. Were you ever deposed in that matter at all?
A. No. In fact, I only heard about it after everything was settled and I got a notification that I was named when I was trying to get privileges at a hospital. I'm going, "What are you talking about?" So I was not even part of the discussion. I didn't know that a lawsuit was even pending.
Q. Would you agree with me that when you serve as an expert in a case in a litigation, it's your responsibility to promote the truth?
A. I think it's my responsibility to promote my opinions, and I believe in my opinions. So it is the truth.

Q. Do you believe it's your role as a litigation consultant to be an advocate or promoter for -- well, strike that. I may not ask it in a compound way.

Do you believe it's your responsibility -- part of your responsibilities as a paid litigation consultant for Ethicon and Johnson & Johnson to be an advocate for that party?

A. Absolutely not.

Q. Do you agree that an expert's opinion should

be unbiased and objective?

A. I do. I think an expert opinion should be unbiased and objective, yes.

Q. Okay. And when you gave your opinions in this litigation, you wanted those opinions to be as accurate as possible; right?

A. Yes.

Q. You wanted to be as thorough in your review of the available information, documents and literature as possible; right?

A. Yes.

Q. And you wanted to make sure that you got all of the information on the pertinent issues in the case before giving your opinions; right?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes.

BY MR. FAES:

Q. Do you feel like you have all of the

pertinent information that you need in order to issue your opinions in this case?

A. I feel as though the documents that I have reviewed are adequate for my being able to form an opinion on these four products.

Q. Is it fair to say that you want to get both sides of the story before issuing your opinions in

this case?

A. I don't really understand what you mean by both sides of the story.

Q. Well, it's fair to say that you want to consider both information that supports your opinions that the TVT devices are safe and effective and you want to look at any information that suggests that the devices are not safe and effective; right?

A. I look at all information, all the information that was provided, yes.

Q. Okay. And you would want to look at all of the information that supports that there might be a defect or problem with the TVT products as well as information that suggests that there isn't a defect or problem with the TVT devices; right?

A. Well, I would like at the quality information; correct. It's a question of all information versus quality information. I'm sure that there's information out there that is not high-quality information. So non high-quality information is -- I

don't think I would put much weight on that.

Q. Okay. What do you consider to be not high-quality information? Do you have any examples of materials in this case that you reviewed that you considered to be not high quality?

A. There's a number of stuff that I've reviewed for this case. Some of it is high quality, some of it is not high quality. I don't have a list of what specific ones offhand.

Q. In general are there any sources or items that you consider to be not high quality?

A. Generally, let's talk about high quality. High quality is like the level 1 type studies, the Cochran databases, the meta-analysis, the statements from the societies. That, I would consider to be higher quality as opposed to non-level-1-type material.

Q. Okay. Do you consider testimony from Ethicon medical directors to be high-quality evidence?

A. Not really, no.

Q. And why is that?

A. Because it's just the opinion of one person, and as opposed to the opinion of a medical society or as opposed to a level 1 research article. A single opinion of one individual is one individual's opinion.

Q. So you consider the testimony of Ethicon's paid medical directors that they hired to be not high

quality; is that accurate?

MR. KOOPMANN: Object to form.

THE WITNESS: I wouldn't place too much value

on that as far as evidence, as far as material that I would use into forming an opinion.

BY MR. FAES:

Q. Okay. It's fair to say that the opinions of Ethicon's medical directors that Ethicon hired and selected to be responsible for the transvaginal mesh products, you don't consider their opinions to be high quality; correct?

MR. KOOPMANN: Object to form.

THE WITNESS: I don't think that the opinion of one person has much value when you look at the body of literature.

BY MR. FAES:

Q. Do you consider internal documents from Ethicon employees such as engineers and people who actually worked on the design of the products to be high quality?

A. Again, that's the opinion of one person. That's not the opinion of a medical society or a large data review. So I wouldn't -- I'd put that as the opinion of just one person.

Q. Okay. So it's fair to say that you don't consider the opinions of engineers who actually worked on the design of the TVT products to be high quality;

correct?

A. Again, that's just the opinion of one specific individual. So when I review material for forming my opinion, I would not base it on one specific individual's conclusions.

Q. I understand that, but my question is a little different and more specific than that.

My question is, do you consider the opinions of engineers who actually worked on the design of the TVT products to be of high quality?

A. I think that it's not that high quality. I think it's just the opinion of one specific individual. I don't put too much weight or value on it. I've looked at those documents and I've kind of looked at them, going okay, that's that guys opinion, or that one's opinion, and okay. But what does the body of literature say, and the body of literature differs from some of those internal documents that you are alluding to.

Q. Okay. What about the -- if it's a -- strike that.

What if we're talking about sworn testimony from an engineer, a person who worked on the design of the TVT products? Is your answer the same with regard to testimony as it is to documents?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes, I would agree. I think they are just the opinion of one individual. So I don't put too much weight on that.

BY MR. FAES:

Q. Do you put any additional weight or consider it to be of higher quality if multiple engineers who worked on the design of the TVT product express the same viewpoint or opinion?

A. Again, it's multiple individuals' opinions.

Q. Do you put any additional weight -- well, I'm going to have to back up, because I'm not sure that exactly answers my question. I understand we're talking about individuals, but my question is a little different.

My question is, does your assessment of the quality of the evidence change if multiple engineers or persons who worked on the actual design of the TVT products expressed the same opinion?

A. Again, I don't put too much weight on those opinions.

Q. But does it change at all? Does it make it more or less credible if multiple persons express the same person?

A. It does not.

Q. Okay. If multiple medical directors for

Ethicon and Johnson & Johnson who were responsible for overseeing the efficacy and safety of the transvaginal mesh products, including the TVT, expressed the same viewpoint, does that change your assessment in any way of the quality of that evidence?

A. It does not. So the evaluation of the TVT and all the products that we're talking about today, there's a body of literature out there that I place a high value on. Individual's specific opinions regarding the TVT and comments that they have made or anything that they've said as an individual, I don't place too much weight on.

Q. Okay. Would you agree that the primary responsibility of Ethicon's medical directors was to ensure the safety and efficacy of the TVT products?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: I do not know what the primary responsibility of Ethicon's medical director is. I can't speak to that.

BY MR. FAES:

Q. Okay. But you've reviewed testimony of some of Ethicon's medical directors; right?

A. I have.

Q. Do you recall reviewing the deposition of Richard Isenberg?

A. The name sounds familiar. I'm terrible with names. So the name sounds familiar, but I'm not sure exactly which one that was.

Q. Do you recall that he was one of the first medical directors for the Ethicon products from approximately 1999 to 2000 or 2001?

A. That sounds about right.

Q. And do you remember him testifying that he considered himself the chief safety officer for the TVT product?

A. Yes, I think that was his opinion.

Q. Okay. Do you have any opinions as to whether or not that's true, that Dr. Isenberg, as the medical director for the TVT products, was the chief safety officer for the TVT?

A. I have no opinion on that.

Q. If he was the chief safety officer for the TVT, does that change your assessment of the reliability of the information that he offers?

A. It does not. I don't know exactly what a chief safety officer entails.

Q. You would agree with me that the medical literature is relevant information that you would want to consider prior to issuing your opinions in this case; right?

A. Say that again?

Q. You would agree with me that the

peer-reviewed medical literature is information that you would want to -- relevant information that you would want to review prior to issuing your opinions in this case; right?

A. I believe I have reviewed that material, yes.

Q. My question was, you would agree that it's relevant information --

A. It is relevant information.

Q. Let me ask it a better way.

A. All right.

Q. You would agree with me that the medical literature is relevant to your opinions in this case; right?

A. The quality medical literature is, yes. Not all of it.

Q. Okay. In your mind, what isn't quality medical literature?

A. The non-level 1, non-peer-reviews, smaller studies, studies that you aren't able to replicate.

Q. And so how do you make an assessment when you are reviewing to the medical literature as to which medical literature is relevant and which is not relevant?

A. I place that the reviews that are the level 1 meta-analysis, the Cochran reviews, I place high value on those. So those are the relevant ones.

The statements of the medical societies,

those are relevant.

Q. What about case reports? Are those relevant?

A. Although I will look at case reports, but it's not a big factor in regards to forming an opinion.

Q. Do you feel that the case reports are relevant information to your opinions in this case?

A. Not really.

Q. So do you just -- do you simply disregard those case reports in issuing your opinions?

MR. KOOPMANN: Object to form.

THE WITNESS: I don't disregard them. You know, I'll look at them. I'm going, oh, you know, I'll present -- may present an idea, it may present a concept, it may present something novel, something new or obscure or rare, and you go, oh, that's kind of interesting, but it's not the basis of my opinion.

BY MR. FAES:

Q. Would you agree with me that testing performed on the TVT products is relevant information that you would want to consider before issuing your

opinions?

MR. KOOPMANN: Object to form.

Go ahead.

THE WITNESS: Say that again?

BY MR. FAES:

Q. Would you agree with me that testing,

pre-clinical testing performed on the TVT products is information that's relevant to your opinions?

MR. KOOPMANN: Same objection.

THE WITNESS: Pre-clinical testing is relevant. I don't think that that's the basis of my opinion. So the basis of my opinion is not going to be based on the pre-clinical testing.

My opinions in this case are based on the clinical application of these devices, and in regards to the source of the information that I get most of it is from that's level 1 peer review journals or review articles or from medical societies. Those are the places that I feel as though provide the best information.

BY MR. FAES:

Q. Is it fair to say, then, that you consider pre-clinical testing to the TVT products to be irrelevant to your opinions in this case?

A. Pre-clinical testings to be irrelevant? I

don't think that it has factored in all that much into -- unless it's factored into these other societies types of data and articles, I don't think it's -- it's the basis of my opinions.

Is there any relevance? Maybe. Maybe.

Q. But as you sit here today, you can't think of any instance or circumstance where a pre-clinical test performed on the TVT products is relevant to any of

the opinions you are offering; is that accurate?

A. Pre-clinical testing? Maybe there's something, but I'm not recalling it right now.

Q. You would agree with me that you would want to understand the differences between the four products that you are offering opinions on before issuing your opinions in this case; right?

A. Say that again, please.

Q. Would you agree with me that you would want to have an understanding of the differences between the four products that you are offering opinions on before offering your opinions in this case; right?

A. In regards to these four products, there's a lot of overlap and similarities between all four of them, and, yes, there are some subtle differences between the two, but generally speaking, they are very similar.

Q. But my question is more, you would agree with me that that's relevant information that you would want to know prior to issuing your opinions, is the differences between the four products that you are offering opinions on; right?

MR. KOOPMANN: Object to form.

THE WITNESS: So in regards to the four products, they are all -- there are very, very subtle differences between them. The relevant differences are actually minimal, but there are some very subtle

differences, and I do believe I am aware of most of them.

BY MR. FAES:

Q. Okay. And my question was, simply, that's information that you would want to know and consider before issuing your opinions; right?

A. As long as it's relevant, yes.

Q. Okay. Would you agree with me that each of the products that you are offering an opinion on in this case, the TVT, the TVT-O, the Abbrevo, and the Exact have different safety profiles?

A. They have different safety profiles, yes, there are.

Q. Okay. Do you think it was important before offering your opinions in this case to understand the

differences between the four products that you are offering an opinion on and other polypropylene midurethral slings?

A. Again, in regards to -- going back to your previous question as well, in regards to safety profiles, there's such overlap and redundancy between all of these products that the way that they are used, their intent for use, the actual materials, that the safety profiles are really very, very similar between all of them. If there are subtle differences between one versus another, the actual relevance of these safety profiles is not significant. That was the

previous question. What was the most recent question?

Q. My question was, do you agree that it's important to understand the differences between the four products that you are offering an opinion on in this case and other polypropylene midurethral slings?

A. These four products and other midurethral slings, again they are all -- the subtle differences between them, although there are subtle differences, I don't believe they are very significant. I believe that there's -- the differences between all of them are minimal and not really clinically relevant.

Q. But you would agree with me that -- well, strike that.

Would you agree with me that it was important for you to know those differences prior to issuing your opinions in this case or do you disagree with that?

A. I don't think that the differences factor into my opinion, so I don't think that they are relevant, despite being subtle differences between all these products. The actual safety and actual intent of use, actually how they are used, they are all pretty much the same. And even in regards to TVT and other non TVT midurethral slings.

Q. And for a number of opinions in your report, you actually are discussing the safety and efficacy profile of midurethral slings in general, not

specifically the TVT; right?

A. Most of it is general, and I do believe that the safety profiles of the TVT does translate to almost all midurethral slings?

Q. Okay. Would you agree with me that the four TVT devices that you are offering -- well, strike that.

Would you agree with me that, for instance, the TVT retropubic device has a different safety profile than say --

MR. KOOPMANN: Wait.

MR. FAES: Strike that. Let me restart a.

BY MR. FAES:

Q. Would you agree with me that the TVT retropubic device, the TVT Classic, has a different safety profile than say the AMS SPARC?

A. Yes.

Q. Would you agree with me that the TVT retropubic has a different safety profile than the Boston Scientific advantage?

A. On certain components, yes. On the basic structure in regards to placement on how they are placed and where they are placed, it's the principles, I believe, are the same for all of these.

However, there might be subtle differences in regards to whether you are taking the transobturator route or the retropubic route, but the sling itself is

the same for all of them. How it's placed and where it's placed, yeah, there are a couple of differences there and things you have to watch out for when you are actually placing them.

However, the actual sling itself is the same for all.

Q. So you would agree with me that the four TVT products that you are offering an opinion on have a different safety profile than other full-length

polypropylene midurethral slings; right?

A. Say that again.

Q. You would agree with me that the four TVT products that you are offering an opinion on in this case have a different safety profiles than some of the other full-length polypropylene midurethral slings that are still on the market; right?

A. I do not. I think that they are pretty much all the same. I think that all midurethral slings, the safety in regards to these products are -- and we're talking about the TVT, the macroporous, all of those, that they are all pretty much the same.

In regards to the subtle differences like with the SPARC and when you asked me earlier with regard to the SPARC and the traditional classic TVT, it's just how it's placed, and that's more of a technical issue of the placement itself than how you are doing it, the mechanics of doing it. It's not at

all for the actual sling itself. The safety profile for the actual sling is similar throughout.

Q. Okay. So when you issued your opinions in this case, is it fair to say that you didn't do a comparison of the safety profile between the -- say the TVT and the TVT Exact sling versus the other retropubic slings that are available?

A. I have looked at literature that does compare different companies' products as well.

Q. Okay. And did you -- what was -- how did you conclude upon looking at that data that there was no difference in the safety profile between the TVT and TVT Exact versus the other --

A. Companies? Sorry.

Q. -- retropubic slings?

A. They are all -- based upon the literature, they are all kind of the same in regards to risks of the sling itself.

In regards to placement of the sling, in regards to where it goes and what structures are involved and the dissection involved and which direction you choose to place the sling, that is different between them.

However, the actual sling itself, they are the same.

Q. Okay. So you said a minute ago all retropubic slings are kind of the same. Are you

saying they are kind of the same or they are all the same?

A. Sorry. All the slings are the same, yes.

Q. For retropubic?

A. For all macroporous polypropylene slings

pretty much -- they are the same. The actual sling itself is the same, how you implant that sling, how you -- where you place that sling, there are subtle differences.

Q. And just to be clear, my question is specific to the safety profile. You are saying that the safety profile is the same of all the polypropylene full-length midurethral slings?

A. Yes.

Q. Is your answer the same if we're comparing the retropubic slings to say mini-slings such as the TVT-Secur, Altis RS?

A. Yes, I believe the safety profile is the same in regards to the sling itself, as opposed to the mini sling which I was not offering an opinion on here today. The mini sling, it's the same material. So I do think that the sling itself is equally as safe as the retropubic.

As far as placement goes, as far as location, as far as how it's placed and the actual placement itself, there are differences between that.

Q. And your answer is the same even with regard

to slings that are no longer on the market, such as the Bard Align or the AMS SPARC; right?

A. I'm not familiar with the Bard Align. I

don't know that one. The other ones. The macroporous, large pore polypropylene, their safety profile is the same for all of these midurethral slings.

Q. Even if they are no longer being sold; correct?

A. The fact that they are being sold or not being sold is -- doesn't factor in.

Q. And you have an understanding that some of the retropubic slings are no longer on the market -- right? -- such as the AMS SPARC?

A. The AMS, Monarc, and SPARC, yes.

Q. And you have an understanding that the Bard a line and the Bard a line TO are no longer on the market. I think you said you weren't too familiar --

A. I'm not too familiar -- sorry. I'm not very familiar with the Bard product. However, the AMS products, I am aware that they are no longer on the market.

My understanding is that it has to do with marketing or business stuff from AMS, but I don't really know too much about that.

Q. And where do you have that understanding from?

A. You know, I'm just kind of guessing, I guess.

I'm just kind of guessing. I'm not 100 percent sure.

MR. KOOPMANN: Don't do that.

THE WITNESS: Okay. Sorry.

BY MR. FAES:

Q. So it's fair to say that -- strike that.

Would the answer to my question be the same if I'm asking if you've done a comparison between -- in terms of the safety profile between the TVT-O and Abbrevo versus other obturator slings that are still on the market such as the Boston Scientific Lynx or any other obturator slings on the market?

A. I feel that they are equivalent in safety.

Q. Okay. So is it fair to say that because you are offering an opinion in this case that the four TVT products that you are offering an opinion on TVT, TVT Exact, TVT-O, and TVT Abbrevo are all safe and effective and they have the same safety profile as other full-length midurethral slings; is it your testimony that all full-length midurethral slings are safety and effective?

A. So as far as all ones, I am not saying all. I don't know what you mean by "all," but I do know that the ones I am familiar with, they are equally as safe in regards to the sling itself. In regards to placement of the sling, again, there are subtle

differences and there are things you need to watch out or look for on the different locations and placement and how they are placed, in regards to the procedure itself, but they are all -- the macroporous midurethral slings, as far as my knowledge goes and my familiarity with the products that are out there, I don't know if there's other products out there that I'm not aware of, so that's why I can't say all.

Q. Well, so it's fair to say that if all midurethral slings had the same safety profile as the four TVT products you are offering an opinion on and the four TVT products you are offering an opinion on are all safe and effective, then all midurethral slings must be safety and effective; right?

A. I would have to review specific -- I did a lot of work on these four specific ones, so I reviewed a lot of information on those. So my opinion today is based on these, but if I were to do a review of those others, I would have to come to that opinion after reviewing all of the literature on those.

So my opinion today is just on these four products. So to place my opinion on other products that are not included in this review would be a little presumptuous, but I do think that midurethral slings made out of macroporous mesh generally are, but I

would have to review all the literature in order to address one specific sling that you are referring to.

Q. In doing your -- well, strike that.

I think you state in your report, if I can find it.

Doctor, in your report on pertaining '2 you state you choose to use Ethicon's TVT, TVT Exact, TVT-O, and TVT Abbrevo devices to treat my patients' stress urinary incontinence; right?

A. What page?

Q. Page 2.

MR. KOOPMANN: I'll object to the form just to the extent I think you said choose and it says chose.

MR. FAES: Oh, strike that. Good catch there, Barry. Thanks.

Q. So your report here says that you chose to use Ethicon's TVT, TVT Exact, TVT-O, and TVT Abbrevo devices to treat your patients stress urinary incontinence, right?

A. Yes.

Q. Do you choose -- do you still choose to use all four of those devices in your practice currently?

A. Currently I'm not using these products.

Q. Okay. Why not?

in Las Vegas practicing here for about three years now, and the contracts from the hospitals were directed toward different products. So the hospitals have now got a better deal from a different product, and that's the only reason why I'm not using any of these products.

Were they available at my hospitals that I work out of, I would absolutely use them.

Q. Well, thank, Barry, I would have blown right past that if you hadn't pointed that out?

BY MR. FAES:

Q. So what products are you using in your practice currently to treat stress urinary incontinence?

A. Currently the hospitals have contracts with a retropubic midurethral sling company and transobturator midurethral sling company named Caldera.

Q. So right now currently you are exclusively using Caldera products to treat SUI; is that accurate?

A. That is accurate. That's what the hospitals have the best contract with.

Q. And specifically what products do they have for the retropubic and the obturator approach?

A. They have, it's a midurethral sling, the Desara.

Q. And the Desara sling, is that for both the

retropubic and the obturator approach?

A. The retropubic is the Desara, Desara blue I've been using, and the obturator one, I forget the name they call it.

Q. Prior to using those devices for the first time, would you have reviewed the IFU or instructions for use?

A. I've used them a long time ago, so at some point in time I probably have looked at the IFU for those.

Q. As you sit here today, can you recall any different or -- strike that.

Can you recall any warnings or precautions that struck out in your mind that was warned of in the Desara IFUs that was not warned of in the Ethicon TVT products?

A. Not offhand, no.

Q. Do you currently treat pelvic organ prolapse in your practice surgically?

A. Yes.

Q. Let me back up before I move on.

I may have already asked this question

before, but I had just -- need to make sure the answer is clear.

Is it accurate to say that currently the Caldera products are the only products that you are currently using for the surgical treatment of stress

urinary incontinence?

A. Right now those are the ones I primarily use. I think since I've been here in Las Vegas I have also used the Boston Scientific retropubic sling as well.

Q. Which is the Advantage?

A. Correct, Advantage Fit, I think they call it.

Q. Just deposed a doctor on the Advantage Fit earlier last week.

A. I believe that's the one.

Q. Okay. Why is it that you -- well, strike that.

You've been in Las Vegas since when? January of this -- of this year?

A. No. I've been here about three years now, a little over three years. 2015 I think I started, June -- no, 2016, '16.

Q. Getting off-track a little bit here, but this letter that she signed with the Washington attorney general's office dated -- is dated December 1st, 2018; is that right?

A. That is correct.

Q. So you were already practicing in Las Vegas at the time that you signed this letter; right?

A. That is 100 percent correct. So what happened with this letter was, I was approached by Dr. Clemons, who I was friends with, and he says, hey, we're putting this letter to go for the AG, you were

practicing here during the period of time that they are kind of looking at even though you have a current license in Washington but you are no longer practicing here, there are still patients of yours that will be involved with this AG suit.

So would you be interested in reviewing this letter and getting onboard with us, so I was onboard with them, even though I wasn't practicing there too. And I told them that, and they said that was fine.

Q. Who said that was fine?

A. Dr. Clemons.

Q. And when you signed this letter -- do you know what date you signed it?

A. I do not know offhand. Whatever it is dated. I was just asked will you be willing to go on it. I said yeah, I do support this, what they are doing.

Q. So did you sign an actual physical document or did you just get permission to attach your name

electronically?

A. Attach my name electronically.

Q. Okay. When you signed -- ultimately signed this letter dated December 1st of 2018, did you still have a current and active license in the State of Washington?

A. As I do now, yes.

Q. Okay. But you weren't currently practicing in the State of Washington; right?

A. No. My practice was here in Las Vegas at that time.

Q. Other than Dr. Clemons' office -- strike that.

Other than Dr. Clemons, did you tell anyone when you signed the letter that you were no longer practicing in Washington?

A. I think I did. I did, yes.

Q. Who?

A. I actually got a call from somebody in the AG's office just to like verify who these people are, and I had just like an informal 20-minute conversation with some lawyer from the AG's office.

Q. Okay. So someone from the -- some lawyer from the AG's office contacted you --

A. Yes.

Q. -- and asked if you would actually sign this letter or not; right?

A. That wasn't the gist of the conversation. They were asking me is this me, what do you think of this, and we just chatted about what my opinions are.

Q. Okay. And what do you remember about that conversation?

A. It was an informal conversation regarding the case that was going on and being on that letter and what my opinions are of the midurethral slings.

Q. Did they tell you that you might be called to

testify in the Washington trial?

A. Yes, they did.

Q. And were you willing to do that?

A. Yes.

Q. So earlier before I got off-track with this Washington letter, I was going to ask you about -- I was starting to ask you about your treatment of patients, surgical treatment for pelvic organ prolapse, and I think you said that you do currently treat patients surgically for pelvic organ prolapse; is that correct?

A. That is correct.

Q. Do you currently use mesh for treatment of pelvic organ prolapse?

A. I use it in sacrocolpopexies.

Q. Okay. So it's fair to say that you no longer use mesh transvaginally for the treatment of pelvic organ prolapse; correct?

A. That is correct.

Q. Was there a time when you did treat pelvic organ prolapse with placement of transvaginal mesh?

A. On specific cases, yes.

Q. And when did you stop doing that?

A. Within the past year. Within the past year the transvaginal mesh for the pelvic organ prolapse was no longer available.

Q. Okay. So is it fair to say that the only

reason that you -- well, strike that. Let me put it in your own words. I think you may have already answered it.

But what was the reason why you stopped using transvaginally placed mesh for the treatment of pelvic organ prolapse in your patients within the last year?

A. In regards to pelvic organ prolapse, I do think that there's a place for transvaginal mesh. I don't -- I think that you need to kind of pick and choose who it would be a good procedure for, and I would kind of pick and choose who would be a good patient, who would benefit from use of a pelvic organ

prolapse mesh and who would be -- who would benefit not from use. So what was your question again? Sorry.

Q. My question was, why did you stop using transvaginally placed mesh for the treatment of pelvic organ prolapse?

A. So in those specific patients that I think they would have been a good candidate for a pelvic organ prolapse for the use of transvaginal mesh, because it's no longer on the market, it's no longer available, so it's not an option anymore.

Q. So is that the only reason that you no longer use transvaginally placed mesh for the treatment of pelvic organ prolapse?

A. I haven't really used a heck of a lot of it

in the past couple of years. And when I did use it it's in very, very specific cases that I do think that the benefits outweigh the risks.

Q. Is one of the reasons why --

A. Sorry. One of the reasons why I cannot offer it to my patients is because it's no longer on the market.

Q. So on prior -- when you did use transvaginally meshed -- strike that. I'm just tripping all over myself.

When you did use transvaginally placed mesh for the treatment of pelvic organ prolapse most recently, what product were you using?

A. Boston Scientific.

Q. Boston Scientific what?

A. Oh, Uphold, I think they called it, the Uphold.

Q. So you weren't just using transvaginal mesh. You were using a transvaginal mesh kit?

A. That is correct.

Q. Okay. But you understand that there are still surgical meshes -- well, let me back up.

Is one of the reasons why, even before you stopped using transvaginal mesh completely, that you only used it in very specific cases was because of concerns over potential complications?

A. With all surgeries I'm worried about

potential complications, and some surgeries have risks that are unique -- that you try to pick the procedures that have the highest benefit and lowest risk.

And in certain cases where I felt that the benefit was there in regards to risks for that unique procedure, that's when I would use it.

Q. So you use mesh currently for the repair of pelvic organ prolapse, but only abdominally; right?

A. That is correct.

Q. Is that because, according to the treatment guidelines issued by ACOG and SUFU that the transvaginal -- strike that -- that the abdominally placed mesh for pelvic organ prolapse doesn't have the same safety concerns as the transvaginally placed mesh for prolapse?

MR. KOOPMANN: Object to form.

Go ahead.

THE WITNESS: Say the question again. I got lost in that one.

BY MR. FAES:

Q. Is one of the reasons that you still use mesh for pelvic organ prolapse implanted abdominally but you no longer use it transvaginally is because there are unique risks associated with the use of transvaginal mesh placement that are not the same as abdominally placed mesh?

A. I think that the -- there are unique risks to

vaginally placed mesh and there are unique risks to abdominal placed mesh, and the mesh that's placed abdominally for a sacrocolpopexy is a very different risk than vaginally placed mesh.

Q. And would you agree with me -- you said it's a very different risk. Would you say that the risk of

complications with an abdominally placed mesh is lower than the risks of a transvaginally placed mesh?

A. I think that the benefits of the abdominally placed mesh are still -- outweigh the risks. In regards to vaginally placed mesh, I think there are some unique risks to vaginally placed mesh for a prolapse that caused it to get pulled from the market, and those unique risks are one of the reasons why it's not on the market and one of the reasons why I can't offer it to those specific patients that I do think would benefit from it. So there are still patients that I see that would benefit from vaginally placed mesh, but I cannot offer it to those patients.

Q. I mean, you would agree that one of the reasons why those products were pulled from the market, was due to safety concerns; right?

MR. KOOPMANN: Object to the form, foundation.

THE WITNESS: Yes.

BY MR. FAES:

Q. And you would agree that at one time the

placement of transvaginal mesh for the treatment of pelvic organ prolapse was thought to be safe and effective; right?

A. I thought -- it is effective. As far as

safety, all procedures have risks associated with it and each different procedure has a unique set of risks associated with it. So you need to kind of look at the patient and evaluate whether those risks are worth it in regards to the benefit.

Q. You would agree with me that at one time it was -- the use of transvaginal mesh for the placement of pelvic organ prolapse was thought to be acceptable for broader use in patients; right?

A. That, I don't know. I don't know what other -- I can't speak to the other surgeons and how they approached it.

Q. Okay. You would agree with me that the understanding of the safety profile of transvaginal mesh for pelvic organ prolapse evolved over time; right?

A. I do know that.

Q. And one of the consequences of the evolvement of that understanding was that the devices were eventually removed from the market; right?

MR. KOOPMANN: Object to form, foundation.

THE WITNESS: I do know that over time that they were thought to be -- that those safety profiles

were an issue and they felt as though that the benefits were not necessarily there and they were

removed from the market.

However, I still do feel as though in specific patients it is still a useful tool to be possibly to offer but in a judicious manner.

BY MR. FAES:

Q. When you use mesh for pelvic organ prolapse repair currently abdominally placed, what mesh are you currently using?

A. It depends on the hospital that I'm operating at. Different hospitals have different meshes out there. I think that certain hospitals have the Coloplast Y-shaped mesh and other hospitals that I work at have the Caldera Y-shaped mesh, but it depends on which hospital I'm at.

Q. What hospitals do you currently have privileges at?

A. I have privileges at probably like seven or eight hospitals here in Las Vegas. I can list them, if you would like.

Q. Sure, go for it.

A. Okay. Valley Hospital --

Q. Unless they are in your CV.

A. They are not in my CV. Valley Hospital, Henderson Hospital. There's two or three St. Rose hospitals, Southern Hills, Spring Valley, Summerlin

Hospital, Centennial Hills, MountainView, Sunrise. I think that's it.

Q. Okay.

A. There are a couple of hospitals that I don't have privileges, but the nature of my practice right now is I'm in a group and we kind of take call and in regards to my practice I don't really get too many E.R. calls or emergencies. However, I do work with gynecological oncologists that service the entire Las Vegas community, and there are some sick patients on their service and they come into different E.R.'s at different times and I need to maintain privileges to round on and see those patients.

Q. So the seven or eight hospitals that you currently have privileges at in Las Vegas, none of those have the TVT products available for use?

A. Not that I'm aware of.

Q. You said that you had occasionally used the Boston Scientific Advantage Fit?

A. Correct.

Q. How many times since you've been to Vegas have you used that?

A. Oh, probably 20.

Q. And why have you used that in 20 cases as opposed to the Caldera retropubic sling?

A. That's what was on the shelf.
MR. KOOPMANN: When you get to a good stopping point, can we take a quick restroom break?
MR. FAES: Sure. Let's just do it now.
(Recess taken.)
BY MR. FAES:
Q. Doctor, we're back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. Currently for pelvic organ prolapse you use the Coloplast wide mesh and the Caldera mesh; right?
A. Correct.
Q. Do you use the Artisyn-Y mesh made by Ethicon at all?
A. I do not.
Q. Do you use the Gynemesh PS mesh or the Prolene soft mesh at all?
A. I do not.
Q. Have you ever used the define owe mesh PS or the Prolene soft mesh?
A. Probably, but in regards to that, it's what the hospitals have contracted out for what's the best deal for them.
Q. Have you ever used the Prolift device?
A. I have not used a Prolift device outside of a

cadaver lab.

Q. So it's fair to say you have never implanted a Prolift device on a live human?

A. No.

Q. Have you ever used the Prosima device?

A. No.

Q. Do you have an understanding that the Gynemesh PS mesh and the Prolene soft mesh is made of the same material at least as the TVT products?

A. If you say that.

Q. So you don't know as you sit here one way or another if that's true or not?

A. I can't verify that.

Q. Okay. Do you have an understanding as to whether or not the Gynemesh PS is still available?

A. I don't know.

Q. You talked about earlier that one of the reasons that you don't use transvaginal mesh for pelvic organ prolapse is that it's no longer available. Do you have an understanding of whether or not the Gynemesh PS or the Prolene soft mesh is still available?

A. I don't.

Q. Do you have an understanding of whether or not there are any meshes available for the

transvaginal treatment of pelvic organ prolapse that

you could use off label?

A. I am sure that there's. However, I don't think that it's available as kits. I think that there are probably -- I'm guessing here. I'm not supposed to guess.

Q. You can tell me what your understanding of the current situation is.

A. My understanding is that there are probably people out there that are kind of doing their own.

Q. It's fair to say -- have you -- well, let me ask two questions.

Have you ever used a flat mesh for the treatment -- for the transvaginal treatment of pelvic organ prolapse?

A. What do you mean by a flat mesh?

Q. I mean, not a kit.

A. I have not.

Q. Okay.

A. For a vaginal placement?

Q. For transvaginal placement, yes.

A. For abdominal placement, I have, yes. Whereas before they were making those Y-meshes, you would have to fashion your own out of a flat piece of square mesh.

Q. Why is it that you have never used a flat mesh for the transvaginal placement and treatment of pelvic organ prolapse?

A. I never felt it was necessary.

Q. Your office is Women's Cancer Center of Nevada?

A. Correct. So the name of my practice is Women's Cancer Center of Nevada. We have a total of eight physicians within our group. The group was started by gynecological oncologists and then as that group kind of -- and they started Women's Cancer Center and as that group grew they added urogynecology, we I have myself and a partner, and they added colorectal surgeons, so we have two colorectal surgeons.

Q. So your primary -- well, strike that.

Is 100 percent of your practice treating women?

A. Yes.

Q. And you are board-certified in obstetrics and gynecology; is that right?

A. That is correct.

Q. Do you have any other board certifications?

A. Female pelvic medicine reconstructive surgery FPMRS.

Q. Is that on your CV?

A. Should be. I am FMRPS certified.

Q. I'm not seeing it on your CV. If you can point it out, that would be helpful.

A. Oh, I didn't put it on there. You know what?

I did not put it on here.

Q. Is this your most current CV as you are sitting here today?

A. You know, it is. Now I know I need to update it. Yes.

Q. And when did you first become board-certified in female pelvic reconstructive surgery?

A. I think it was 2015 or '14. I don't remember the exact year.

Q. Okay. So Fairly recently within the last three or four or five years?

A. When it became available as a subspecialty, yes.

Q. Do you regularly treat cancer patients?

A. When I'm on call. I will not treat cancer patients, but I will round on my partners' patients and I have an oncologist backup. So when we take calls, I see their postop patients, but I don't treat cancer.

Q. What percentage of your patients do you treat

for stress urinary incontinence?

A. You know, I can't give you an exact percentage on that. The bulk of my practice is pelvic organ prolapse and urinary incontinence. So I would say over 80 percent of my practice is either pelvic prolapse or incontinence.

Q. And how many days a week do you typically do

surgery?

A. Typical surgery, two to three days a week.

Q. How many -- on a typical week, how many surgeries do you do for stress urinary incontinence?

A. Anywhere from two to eight.

Q. And of those two to eight surgeries, are all of those usually for the -- well, currently it would be for putting in a Caldera sling; right?

A. That is correct.

Q. How often do you do surgeries on a typical week for pelvic organ prolapse?

A. Again, pelvic organ prolapse, I would say four to ten.

Q. And of those four to ten, what percentage of those typically involve the use of a surgical mesh to treat the pelvic organ prolapse?

A. On a typical week, zero to one.

Q. So it's fair to say that you use, even

abdominally, mesh for the repair of pelvic organ prolapse rarely; right?

A. No. I think at least, you know -- last week I did two of them. This week, I don't know. I didn't look at my schedule, but maybe I have zero or one. Next week I'll have two. So it's pretty regularly. On a regular weekly basis I'll do zero to two.

Q. Okay. So in what percentage of cases where you treat pelvic organ prolapse would you say that you

use mesh?

A. I would say, oh, 10 percent.

Q. Okay.

A. 5 to 10.

Q. And the number of --

A. 10 percent.

Q. The number of surgeries that you are doing implanting slings, which I think you said was 2 to 8 a week?

A. Yeah.

Q. -- has that remained pretty consistent over the 12 years you've been practicing or has it changed over time?

A. It has changed over time.

Q. How has it changed over time?

A. I'm way busier here in Las Vegas, so here in

Las Vegas there's a large patient population that's retired that kind of moves here, so there's a lot of older active women that have incontinence.

Another thing about this market here in Las Vegas is that there's not too much of us that are urogynecologists here in town, so it's not really a saturated market. So I get a higher volume of those incontinence patients.

When I was in Seattle, it's a much younger city and there are a ton of other docs that do exactly what I do within a smaller geographic area. So it was

slower up there.

Q. So Las Vegas is a gold mine for somebody who puts in slings. You don't have to actually answer that.

A. It's a decent community. It's actually a really nice community. You get all these retirees from the cold states, Ohio, Michigan, all those state -- Pennsylvania, and they retire with pensions. It's a relatively inexpensive place to live, the income taxes are pretty decent, so they kind of move here, and they go back and visit wherever they are from during the summer when it's 115 here, but during the rest of the year they are active, they are busy people, and they like to have a nice quality of life.

Q. And what percentage of your --

A. But I wouldn't call it a gold mine.

Q. That's fine.

What percentage of your practice would you say is treating mesh complications?

A. I see a few a week, a couple a week.

Q. And how often would you say that you need to treat a mesh complication surgically, meaning you have to return to the operating room either to excise mesh or revise mesh?

A. I would say a couple of times a month. I do think that within this community, because there are few providers that I was talking about, I do think

that I get funneled a lot of those cases.

Q. So it's fair to say that you -- strike that.

It's fair to say that you treat a complication from a mesh surgically by returning to the operating room to excise or otherwise revise the mesh approximately 12 to 24 times a year?

A. Closer to the 24.

Q. Okay.

A. I would say 24 is a decent...

Q. And has that number remained consistent over the 12 years that you've been practicing?

A. Again, it's when I was here in Las Vegas it's

remained consistent and when I was in Seattle it was lower.

Q. Okay. But you've been here -- has it remained consistent in the three-plus years that you've been here?

A. I think initially it was probably less.

Q. Uh-huh.

A. And the reason why is because I'm new to town and I don't know the referring providers and I haven't met all the folks that are out within the community. Now that I'm a little bit more established here and people know who I am, I think I get more of this.

Q. But it's fair to say it has been at least 50 times that you have removed a pelvic mesh in the operating room; right?

A. That's a decent guess, a decent estimate.

Q. And that's approximately 50 time -- well, strike that.

Of the times that you have surgically removed mesh in the -- transvaginal mesh in the operating room, do you know what percentage of that was a sling versus a transvaginal POP mesh?

A. I do not.

Q. What's the primary indication for the transvaginal mesh removals or revisions that you've

done, typically?

A. It's mostly mesh exposures.

Q. Okay. You would agree with me that one of the other -- strike that.

You've also removed or revised meshes, slings if someone has gone into urinary retention; right?

A. Yes.

Q. And you have an understanding that a sling can tighten up and cause urinary obstruction or retention later on even if the sling is placed perfectly by the surgeon; right?

A. So long-term urinary retention after time, I haven't seen too much of that. The typical retentions that I see are in the immediate postop period of time. In fact, I'm trying to think back on one. Nothing is popping into my head about a long-term one.

Q. And when you say the immediate postop period,

do you mean four to six weeks?

A. Anywhere from zero to eight weeks, one to eight weeks.

Q. Do you have an understanding that even if a sling is placed perfectly by a physician, that a sling can become tightened up and cause urinary retention even after the immediate postoperative period?

A. I haven't seen too much of that outside of

that immediate postoperative period of time, and if that does happen, it's an infrequent event.

Q. Would you agree with me that a return to the operating room for urinary retention following placement of a polypropylene midurethral sling is a risk that's unique to midurethral slings that you don't see with Burch?

A. No, not at all. Burch also has that risk too.

Q. If you look at page 11 of your report, you've got a listing here for return to O.R. for urinary retention and the rate for Burch is 0 percent, according to your report; right?

A. Yes. But with all antiincontinence procedures there's a risk.

Q. Well, 0.0 percent is basically unheard of with Burch; right?

A. That's what it says, yes. I think I was quoting a study here. Let's see. Let me take a look

here. (Document review.)

If you go earlier in the thing -- can I read this to you? It says, "Rate of urinary retention lasting longer than six weeks in retropubic midurethral slings like the TVT is only 2.7 percent lower than that seen with pubovaginal slings,

7.5 percent, and the Burch procedure, 7.6 percent.

And you know what? It's the same article, so I think that there's a typo someplace. It's the Meagan Shimp article, 2014. So it's 7.6, and I think that may be a typo.

And so it's the urinary retention 7.6 percent but then return to the O.R. is zero percent. So I have to look at that article again but I think they were probably looking at that there's retention but it was managed without return to the O.R., it was managed differently.

Q. So my question is, urinary retention with a Burch that requires a return to the O.R. to treat it is basically unheard of; right?

A. You know, I would have to look at that article again, but it is -- it lists the urinary retention at 7.6, but I would have to look at the article one more time to kind of confirm that. I don't know if that is a typo or not.

Q. I should have asked this earlier in the day, but what did you do to prepare for your deposition

here today?

A. What did I do to prepare?

Q. Uh-huh.

A. I just kind of read over my report, looked

over some of the articles that are involved.

Q. And what articles did you look at in preparation for your deposition today?

A. I don't remember which specific ones. I kind of randomly picked a couple.

Q. We marked earlier some of the items that you brought in response to your deposition notice, but I also notice that there's some gigantic binders here as well.

Are those items that you reviewed and relied on for issuing your opinions in this case?

A. That's part of it, yeah.

Q. I see three binders here. Well, there's one over there too (indicating)?

MR. KOOPMANN: That's mine.

BY MR. FAES:

Q. Are these all different binders?

A. Yes.

MR. KOOPMANN: Andy, I can probably help with this if you want me to.

MR. FAES: Sure.

MR. KOOPMANN: So this one (indicating) contains his report, his CV, his -- and the materials

cited -- and his reliance list and then the materials
cited in his report.

MR. FAES: Okay.
MR. KOOPMANN: These (indicating) are just miscellaneous documents that he's been provided.
And then all of this is included on this thumb drive now (indicating) that's been marked as Deposition Exhibit 9.
BY MR. FAES:
Q. If you are aware, is there anything in these three binders that isn't on your supplemental -- that isn't listed on your supplemental reliance list that we marked as Exhibit Number 5?
A. Exhibit Number 5, I think that the -- I'd have to actually compare between the two, but I think the thumb drive has a bunch more stuff on it.
MR. KOOPMANN: I'll represent to you that the supplemental reliance list should contain everything that's in these binders.
BY MR. FAES:
MR. FAES: Does the supplemental reliance list contain everything that is on the flash drive or is there stuff on the flash drive that isn't on the reliance list?
MR. KOOPMANN: There should not be. The flash drive should contain everything he's been sent. The flash drive also contains his -- the notice for

the deposition, his report, CV, his reliance list, the materials cited in his general report, and then a copy of all of the materials he's ever been sent regarding general non patient specific information.

BY MR. FAES:

Q. You are currently licensed to practice in the state of Nevada and Washington; right?

A. And Texas.

Q. And Texas. Any other states where you have been licensed in the past?

A. No, that's it.

Q. Are all those licenses in Texas, Washington, and Nevada still active?

A. They are active and you just reminded me I have to renew my Texas license.

Q. Prior to being engaged as a litigation consultant in March of last year, had you ever had a consulting agreement or relationship with Ethicon or Johnson & Johnson?

A. No.

Q. So you had never been a preceptor or a person who gave talks or did cadaver labs for Ethicon and Johnson & Johnson?

A. I have not.

Q. Did you ever receive training from Ethicon

and Johnson & Johnson on any of their products?

A. Yes.

Q. And one of them was the Prolift right because you went to a cadaver lab?

A. Correct.

Q. What other products have you received training on from Ethicon and Johnson & Johnson?

A. I think pretty much everyone. TVT, TVT-Os, TVT Exact, Abbrevos.

Q. Secur?

A. Secur.

Q. Prosima? You said you had never used one, so I'm assuming not.

A. No, I don't think I got that one.

Q. So you were trained on Prolift but you never actually used it; right?

A. That's correct.

Q. Is there any particular reason why you never chose to use the Prolift device in your practice?

A. I didn't think it was -- I never really got good at it. I went to a course and I said okay, I understand that it's out there, but I think that what I'm doing and in my hands, it's not necessary.

Q. Okay. What -- other than the Uphold device, what other products have you used for the treatment of

pelvic organ prolapse mesh products?

A. I think I've used a Coloplast one, and I forget what they call it.

Q. So do I. If I thought really hard I could probably come up with something. Nova sill?

A. Doesn't sound familiar. It doesn't ring a bell.

Q. That's one of them?

A. But I have used the Coloplast one.

Q. Is Uphold the only one that you used regularly for pelvic organ prolapse?

A. Yes, but I wouldn't even call it regular use.

Q. Okay.

A. It's a sporadic, case-specific type of a use.

Q. How many times would you say you have used the Uphold during the course of your 12 years practice? Less than 20?

A. Probably around there.

Q. Okay.

A. Probably more than 20, but not that many.

Q. Have you ever had a -- been a preceptor or teacher for any other mesh manufacturer, whether it be AMS, Astoria ^ , Bard, Coloplast, Boston Scientific?

A. No.

Q. But you -- other than the -- you've used the

Q. Why did you stop using that device?
A. I didn't think it worked as well as the others, and I thought that my outcomes with the other TVT products was really good and the complications rate really low, so I said I'm going to stick with what I -- works best in my hands.
Q. Did you implant the TVT-Secur in any actual patients prior to making the decision to discontinue it?
A. Maybe one or two, but very low -- no. More than that. A handful. I don't know. It was a long time ago.
Q. Other than the TVT family of products and the Caldera and the Advantage Fit, what other polypropylene slings have you used for the treatment of stress urinary incontinence?
A. Let's see. There's a Coloplast one I've used.
Q. The Altis?
A. Yes, that one. Let me think. The Monarc.
Q. SPARC?
A. SPARC. That's it. I think that's it.
Q. What about the MiniArc PRO?

A. I don't remember which one that was. They all kind of blend together.
Q. Do you remember if you attended a training session for that in 2014 that you were reimbursed for?

A. I don't know. Was I? I may have been. In 2004?

Q. '14?

A. I may have been. Which one is the MiniArc Pro. Who is that made by?

Q. Well, AMS and later on Astora?

A. Yes, I do remember that one, so I probably did go to that.

Q. Is it a device you ended up using in your practice?

A. No.

Q. But the Altis, you did ultimately use in some patients?

A. I think I have used the Altis, yes.

Q. Other than Ethicon and Johnson & Johnson, have you been a retained consultant for any other pharmaceutical or medical device companies?

A. No, I have not.

Q. You haven't been a consultant for Intuitive Surgical?

A. Consultant for Intuitive Surgical? No, I've

never been reimbursed for anything from Intuitive Surgical. At one point in time, one of my partners was a consultant, and I may have been listed on their list of consultants because we kind of all saw the same patients. I have never received any payment from Intuitive Surgical for consulting fees, but I was in a

group with another gynecological oncologist that I think was a consultant, and I think I got roped into that contract. So I may have been on their list of consultants, but I've never received anything from them.

Q. Regardless of whether you received anything from them, have you done any actual consulting work from them?

A. Not that I can remember. It may have been kind of roped in within my group where the other partner was kind of the lead person on the consulting part, and maybe I've seen a patient or is listed as taking care of some of those patients, and that may have been part of the consultant -- but honestly, I was not in an active role at all.

Q. Do you have an understanding of the Center For Medicaid maintains a database of payments that have been made to various physicians?

A. I am aware of that. If it is, it was a long

time ago.

Q. Okay.

A. Did I receive anything from them?

Q. Well, according to the --

A. I don't recall.

Q. I'll represent that according to the CMS website you received $12,000 from Intuitive Surgical in 2017?

A. 2017?
Q. Yes. And 3,000 in 2018.
A. No. 2017?
Q. Yes.
A. From Intuitive Surgical? I did training with them in 2017, but I have never received a payment at all. Maybe that was part of training courses or them sending me to Intuitive to do a robot course and take a robot course, and that would be the cost of that. But I have not received anything financial from them. Whether they consider me a consultant by kind of bringing me there to do a pig lab with them, I have done a pig lab with them, and I think that was in 2017.
Q. Is it fair to say that you probably didn't do $12,000 worth of training with them, right, where you would be reimbursed that amount?

A. I do know that those courses are very expensive. You go to their mother ship and have a course on it. I don't know how they kind of bill or do any of their accounting for it. They may do it that I'm a consultant, but I have never received any sort of cash payment from Intuitive Surgical. Anything that I have received from Intuitive Surgical has been in the form of education.
Q. And the education or training that you were receiving from Intuitive Surgical, would that have

been on a Davinci robot?

A. That's correct.

Q. Is that something that you have ultimately chosen to employ in your practice?

A. I do, yes.

Q. And other than -- I assume you use it from your abdominal sacrocolpopexies.

A. That's correct.

Q. Is there anything else you use the Davinci robot for?

A. Hysterectomies, uterosacral suspensions.

Q. Regardless of whether or not you have been a paid consultant for any other pharmaceutical or medical devices, it's fair to say that you have attended a number of events or received reimbursements

from a number of different companies; right?

A. Yes, that is true, in the course of training I have gone on weekend type of things where they bring you up on a Sunday and they have a course and they train you. I'm planning on doing one in October as well.

Q. Okay. It's fair to say that you have received payment or training from Coloplast, which is the mesh company; right?

A. Training only. Not payment. And if there's payment it involves like reimbursement for a hotel or a flight or a meal, whatever you submit to them,

they'll reimburse you, but it's all regarding training. I would assume that the Intuitive Surgical one is the same.

Q. Okay. It's fair to say you received training and/or reimbursement from AMS which later became Astora Health; right?

A. Yes. Not payment. Again, it's training or reimbursement regarding a training.

Q. It's fair to say that you have received training and/or reimbursement from Boston Scientific; right?

A. Again, it's the same thing.

Q. Received training and/or reimbursement from

Caldera?

A. Again, it's the same thing. I don't quite remember, but I'm sure I've been -- as new products kind of come out there, one of the ways you can learn about these products is by going to cadaver labs that they have set up, and it's part of training. All that's reportable?

Q. Is it fair to say that they paid or reimbursed over $2,000 of training, Caldera did, in 2017?

A. 2017?

Q. Yes.

A. Yes, probably, a new sling, a new -- yeah.

Q. Is it fair to say that Coloplast either paid

for training and/or reimbursement for you of over $2,000 in 2017?

A. Sure.

Q. It's fair to say that you have received training and/or reimbursement from Allergan?

A. Probably right.

Q. And probably in conjunction with Botox, which is something that you --

A. Yes.

Q. -- offer your patients?

A. Yes. Sorry, sorry, sorry.

Q. Is it fair to say you have received training and/or reimbursement from Merck?

A. You know, I don't -- you probably have better information than I do on regarding all of those. So I would assume, yes.

Q. Do you remember attending or going to an event regarding Keytruda for them?

A. Keytruda.

Q. Uh-huh.

A. No.

Q. K-e-y-t-r-u-d-a.

A. Whatever it is, I don't use it.

Q. Okay. Is it fair to say that you have received training and/or reimbursement from Amgen?

A. I don't remember.

Q. Is it fair to say that you have received

training and/or reimbursement from Pfizer?

A. Again, I don't remember. Probably. All of those listed are in the form of training. So I have not received any sort of reimbursement. So in regards to when different companies have new products and they want you to learn about them, they are able to provide you with an opportunity to learn about them, and there's an educational cost associated with it, so I'm assuming that that's what it is.

In regards to reimbursement, all reimbursement has been in the form of those types of training situation. I've never received anything as far as a check or compensation for any sort of expertise.

Q. Sometimes they --

A. Maybe -- sometimes they buy you a book too, and that may pop up over there sometimes as well. If they buy you like, oh, the new textbook on anatomy for netter is out and they say would you like a copy? Sure.

Q. Is it fair to say sometimes they provide or reimburse you for food and beverage at those events?

A. Probably. Typically, those events, let's say -- I have one coming up, and it's for InterStim, and they will pay for my flight to where the meeting is. They'll put me up in a hotel the night before, and the next day I have a training session and

typically there's a dinner or some sort of a social activity the night before the event, and I'm sure that that falls all under the heading of reimbursement for training, but it's all in the form of training. I've never received anything from any company as a mentor or proctor or teacher. I've always been on the learning side.

Q. Okay. It's fair to say that you have gone to events for Medtronic; right?

A. Uh-huh.

Q. For Shionogi?

A. I don't know what that is.

Q. S-h-i-o-n-o-g-i.

A. I may have.

Q. Okay. Do you remember going to training or an event --

A. I want to write down Shionogi. I don't know what that is.

Q. It's on your 2014 payments. You know that the list of payments or reimbursement or other in kind payments you have received from pharmaceutical device companies you can dispute that if you think it is incorrect with the centers for Medicaid?

A. I'm aware of that. A lot of times also in our office, because I have gynecological oncology partners and I have colorectal partners, sometimes the pharmaceutical companies and drug companies will bring

lunch to the office, and if I eat lunch at the office I sign the little sign-in sheet, so I think that gets flagged too.

Q. Have you ever gone to an event or any kind of speaker training for the INSYS for the SUBSYS product?

A. I don't remember.

Q. Do you know what the SUBSYS is?

A. Which one is this?

Q. It's a fentanyl spray made by INSYS?

A. Oh, they were a lunch. How much was that one?

Q. Fifteen dollars.

A. Yes, that was a lunch. Yes.

Q. Have you ever prescribed the SUBSYS product to any of your patients?

A. I have not, but my partners do. My partners are gynecologic oncologists and they --

Q. They treat cancer. They probably --

A. Yes. So I signed the sign-in sheet.

Q. Okay. Do you remember going to any kind of a training for -- or an event for some sort of an electric scalpel, made by Ethicon?

A. Made by Ethicon, an electric scalpel? Recently I was talking to a rep in regards to a radio-frequency scalpel.

Q. Do you remember what the name of that one was?

A. No, I don't.
Q. I forgot to write the name down.
A. I don't remember. That was a Medtronic

product and I think I may have been just talking to somebody hey, what are your other products?" Oh, that's kind of cool."
Q. Have you ever -- and I don't see it in your CV. Have you ever published any peer-reviewed articles regarding any of the mesh slings?
A. No.
Q. I notice from your CV that you have been trained and have used the Burch procedure for stress urinary incontinence; right?
A. Yes.
Q. Have you been trained or used the technique of an autologous fascial sling --
A. Yes.
Q. -- in order to treat stress urinary incontinence?
A. Yes, I have.
Q. When was the last time you have performed a Burch procedure?
A. Oh, probably 2006.
Q. When is the last time you did an autologous fascial sling procedure?
A. Again, probably 2006.
Q. Where were you practicing in 2006?

A. In Texas in fellowship.

Q. I guess you are fairly young. That's only 20 years ago.

Would you agree with me that the Burch procedure for the treatment of stress urinary incontinence is still within the standard of care today?

A. I think people still use it. I think people still use it, but I do think that midurethral slings are a\far better route to go for stress urinary incontinence.

Q. But if a physician were to perform the Burch procedure for the treatment of stress urinary incontinence today, would you agree with me that that would still be within the standard of care?

A. I think the standard of care is a midurethral sling. I think the standard of care is a midurethral sling. Is a Burch procedure an option for certain surgeons? Sure. That's up to them.

But in regards -- in my practice and in regards to my understanding of how most physicians and surgeons that take care of urinary incontinence, I would say that mine and my colleagues' standard of care is a midurethral sling.

Q. Would you agree with me that if a physician chose to use the Burch procedure for the treatment of

stress urinary incontinence today, that would not be below the standard of care?

A. Well, you know, I don't know, on that. I don't want to, like, argue with a different surgeon, but I do think that they are choosing a procedure that has more morbidity and less efficacy, so I would kind of wonder why they would choose a procedure that didn't work as well and that has more morbidity. So I do think it's probably below the standard of care. I don't think standard of care is kind of like this written-in-stone thing.

I think that most contemporary active surgeons that take care of stress urinary incontinence would use a midurethral sling. I think that if you use a Burch procedure as your primary procedure for stress incontinence you are an outlier, it's an outlier. I would say it would lie outside the standard of care.

Q. So it would be your opinion that a surgeon that uses the Burch procedure for their primary procedure currently is not a contemporary active physician?

A. No. I think there are a lot of contemporary active physicians that do use Burch procedures, but I think those physicians would be considered an outlier

in regards to how to address stress incontinence. I think in their hands they think that is the best for their patients, but I think that the bulk of surgeons that take care of stress incontinence will choose a midurethral sling for their patient -- for most of their patients.

Q. Well, do you believe that being an outlier or someone who doesn't go with conventional wisdom with regard to a surgical procedure is falling below the standard of care?

A. You keep referring to the standard of care as this rock-defined thing, and I don't really have a black-and-white definition of standard of care. I don't really know if there's a black-and-white definition of -- however, I would think that in -- if I were talking to a colleague and they said that they still did a Burch procedure as their primary procedure, I would think that they are not choosing the optimal -- not choosing the best procedure for stress urinary incontinence due to the efficacy and complications.

Q. So if I understand you correctly, you are saying that you don't have a black-and-white definition of the standard of care. Is that accurate?

A. No. I mean, I do think that the midurethral

sling is the -- the reason why I'm kind of dancing around this is I hate to criticize other physicians and other surgeons in their choice on what to do for their patients and I hate providing commentary for -- if it's a colleague or somebody if that's what they think is best, but it's my opinion that the standard of care today for stress urinary incontinence is a midurethral sling and I would say that the surgeon that chooses a Burch procedure for a midurethral sling is kind of -- is performing outside the standard of care.

Q. So it's -- is it your opinion that a physician that chooses a Burch procedure over a midurethral sling is essentially committing malpractice?

A. No, absolutely not.

Q. Would you agree with me that using --

A. I don't think that it is malpractice, but I do think that it's an option that they can pursue for their patients, but I think that there are better choices.

Q. Do you believe that the Burch procedure is a reasonable treatment option for a patient who does not want mesh for the treatment of their stress urinary incontinence?

A. Yes.

Q. If a patient came to you and after going

through the various options and informed consent with you, they told you that they didn't want to have a mesh sling for the treatment of their stress urinary incontinence, what other options would you present to them at that point?

A. I would be hard-pressed to perform a Burch procedure now, and the reason why is because I would tell them, I would say, look, there's a better procedure out there that holds less morbidity, that works better than a Burch procedure. So in my practice and with my patient in front of me, I would say I wouldn't want to do a Burch procedure on you simply because it's -- I have a better option and I wouldn't want to do a procedure on a patient that I think is going to have a higher risk with a lower efficacy. And if there are concerns about the mesh, I would try to address those concerns specifically.

Q. If a patient ultimately decided that they wanted to proceed with a non-mesh surgery for their stress urinary incontinence, whether it be a Burch procedure or an autologous fascial sling, would you refer that patient to another doctor in order to perform those procedures?

A. I wouldn't refer, but I would try to convince them that there's better procedures out there and I don't feel comfortable performing a procedure on somebody that has better options.

Q. When you --

A. If they choose to pursue treatments elsewheres, I guess that's up to them.

Q. When you present surgical treatment options for the management of a patient's stress urinary incontinence during your informed consent discussions is the polypropylene sling the only surgical option that you present to your patients?

A. I present them the best option out there, and that is the best option. So do I present them with alternative options? No, typically I do not, and the reason why is because I do think that this is the best option for patients.

I mean, they used to do MMKs in the past too for -- and I don't think Marshall Marketti and Krantz are doing MMKs either, because there are better options out there.

Q. So after having an informed consent discussion about the risks and benefits of mesh surgery, a patient said no, thank you, Doctor, I would like a different option than mesh to treat my stress

urinary incontinence, would you tell them about other surgical mesh procedures or would you just say well, that's the only option I have?

A. No. I would tell them, I would say, look, the mesh procedure is the best, least morbid, most effective procedure out there. There are other

options, there are other alternative procedures for stress incontinence, however, they are inferior procedures and I don't feel comfortable performing an inferior procedure on you to address something.

Q. If a patient asked what those inferior procedures are, would you describe those -- what you believed --

A. Sure.

Q. -- are inferior procedures to them?

A. Yes, I would.

Q. And what are the other alternative procedures that you would describe?

A. The ones we just talked about. There's a Burch procedure, autologous sling. I wouldn't bring up an MMK. Those procedures are really not good.

Q. Okay. And if upon hearing those alternative options of a native tissue sling or a Burch procedure, a patient was interested in those options and wanted to explore them further, what would you do at that

point, other than try to convince them that the sling is a better option?

A. You know, I'd have to be in the situation and really talk with the patient to get a sense of understanding. So honestly, I don't know what I would do.

Q. But ultimately, if a patient came to you and said, look, Doctor, I've researched the options on my

own and I want either a Burch or a native tissue sling, you would essentially at this point refused to either of those procedures on your patients?

A. I would do my best to convince them that there are other procedures out there that are superior. Would I do that? It depends on the patient. It depends on what's going on. It depends on the larger clinical picture, but it is something that is available but I don't think is the optimal choice.

Q. Do you feel like you could still do a -- competently do a Burch procedure or a native tissue sling despite not having done one since 2006?

A. Burch procedure I could do. Burch procedure I could do. Yeah, I could do both of those, yes. They are both -- technically they are not that challenge of a procedure, so yes, I could do both.

Q. So if a patient ultimately insisted on one of those procedures, would you attempt to do those procedures yourself, or would you feel more comfortable referring that patient to a physician that has done them more recently?

A. In this community here in Las Vegas, I don't think anybody has done them recently. So I think -- I feel comfortable doing those procedures. Even though I haven't done them in a while. It's because there's better choices out there. But if there was a patient

that was insistent upon it and they understood the risks associated with it, I guess I would, but I'd really try my best to have them have a procedure that I felt was superior.

Q. Is it true that you've never written a peer-reviewed journal article on polypropylene mesh or any devices using polypropylene mesh?

A. I mean, I'm familiar with all of the literature, but I personally have not written an article.

Q. Is it true that you aren't doing any current research on any polypropylene meshes?

A. At this time, my practice is a clinical-based practice, I'm in a private practice where research in regards to mesh I'm not an active part of. However,

Caldera has been collecting some -- asking for some research data stuff because I do a high volume of sling placement, so I think my group or my partner has enrolled and I may be listed on there as well, but I haven't enrolled any patients in the study that they are looking for.

Q. So currently you are not doing any research on any polypropylene meshes; right?

A. I'm not doing -- right now I'm just trying to build my practice as a clinician and I'm not doing any active research at this time.

Q. It's true that you have never written any

kind of journal article on the Burch procedure; right?

A. I've not written an article on the Burch procedure; that is correct.

Q. And it's true that you have never written any journal articles on the pubovaginal sling; right?

A. I have not; that's correct.

Q. Do you have any -- it's true that you don't represent yourself as a chemical engineer? Right?

A. As a chemical engineer?

Q. Yes.

A. I mean, I'm familiar with the materials that are involved with products that I use, but do I make a living as a chemical engineer? I do not.

Q. You don't have any background or training specifically in chemical engineering; right?

A. I mean, I'm familiar with what's involved in regards to the products that I use, but like I said, it's not a -- someplace where I -- I seek employment or lay my flag out as a chemical engineer.

Q. Right. You've never represented yourself to anyone or the public as a chemical engineer?

A. I have not.

Q. You have never represented yourself as an expert in chemical engineering; right?

A. An expert in chemical engineering? I do think that I'm familiar with what chemical engineering is, I'm familiar with the product, the chemical

background in regards to the products that I use, but have I ever sought employment as a chemical engineer or stated to the world that I am a chemical engineer, I've never stated that I'm a chemical engineer, but I'm familiar with the background in regards to the products that I use.

Q. You have never represented yourself as a surgical pathologist; right?

A. Again, I have worked with surgical pathology on a routine basis, whether it's from hysterectomies to removal of slings, anything like in regards to

that, however, so I am very familiar with surgical pathology, so I do think I'm an expert at surgical pathology, but I've never sought employment as a surgical pathologist. I've never received compensation as a surgical pathologist, but I do think I'm very familiar with surgical pathology.

Q. You would agree with me that surgical pathology is a different subspecialty than any of your current specialties; right?

A. Surgical pathology is a residency, and I did a residency in obstetrics, gynecology, and a fellowship in female pelvic medicine and reconstructive surgery, so no, I did not do a fellowship in surgical pathology.

Q. And you mentioned that you regularly review reports from the pathology department as part of your

practice; right?

A. Yes. The bulk of what I do is review reports. Sometimes you talk to the pathologist and you can get more information from the pathologist.

Q. Do you ever review the actual histopathologic slides?

A. In regards to reviewing the actual slides themselves, typically I do not, so I do rely on colleagues for looking at the slides themselves. I

have looked at slides in the past, but routinely I don't necessarily look at slides, but I have looked at slides and pathology.

Q. Okay. But in general, your work in pathology is generally limited to reading the reports of the pathologists who have had specialized training in that field; right?

A. It's reading the reports, it's collaboration with the pathologist to provide clinical context, it's discussions with the pathologist, it's kind of talking with the pathologist, if they make a call on something and you say, hey, this is the clinical situation and they go, oh, well, that changes things a little bit, and they can -- they do adjust for things, so it's more of a collaborative relationship with surgical pathology.

Q. Do you have any background in polymer chemistry?

A. Polymer chemistry? Polymer chemistry, not any professional background in polymer chemistry. Again, in regards to the materials that are involved in products that I use, I'm familiar with them. I know how these products are made and I'm aware of the process that goes into them, but have I ever -- again, have I ever sought employment or claimed to set myself

out as a polymer chemist? I have not.

Q. Okay. Is it fair to say that you have never held yourself out as an expert in polymer chemistry; right?

A. As far as the -- in context of the materials that I use, I am aware that -- the polymers that are involved in the products that I use and the polymers and process that goes on with them is -- I'm very familiar with those.

But as far as claiming to be -- I do feel as though I have expertise in the products that I use. However, am I this professional polymer chemist? I am not.

Q. You said you are aware of the polymers in the products that you use?

A. That was kind of misspoken. So I'm aware of the process and what goes on into production of the products that I use.

Q. Explain to me the process that goes on in the production for the TVT products.

A. The actual day-to-day production, I do not know, I do not know.

Q. Okay. Do you know what kind of a polymer that the TVT products are made from?

A. Polypropylene, is that what you are referring

to?

Q. They are made from polypropylene. Do you know who supplies the polypropylene material or where that comes from?

A. Oh, like I'm terrible with names, Synoco, Synookoo, Sunnico, one of those names (phonetic).

Q. Do you know who supplies the -- strike that.

Do you know what kind of polymer is in the Advantage Fit product that you use?

A. It's polypropylene.

Q. But do you know -- you know there's different kinds of polypropylene; right?

A. Yes.

Q. Do you know specifically what kind of polypropylene it is?

A. You know, I don't know, with the Advantage Fit offhand.

Q. The Caldera slings are a product that you use; right?

A. Yes.

Q. Do you know what kind of polymer or polypropylene is used in that product?

A. I know that it's a polypropylene product, you know, Type I classification type of a product. What specifically are you referring to?

Q. Well, I'm just referring to the statement that you said you are aware of the polymers in the products, so I'm asking you do you know what polymer specifically is in the Caldera product that you currently use?

A. It's polypropylene.

Q. But again, there's different kinds of polypropylene. Do you know what kind of polypropylene it is?

A. I'm not aware of which unique type for each different one.

Q. Do you know if it's different from what's in the Ethicon products?

A. It's a similar polypropylene. They are all a polypropylene mesh.

Q. Do you know if the polypropylene in the Advantage Fit product is different than what's in the Ethicon products?

A. There may be subtle differences regarding the treatment and the process, but it's my understanding that it's polypropylene.

Q. You've never done any kind of analysis of the chemical differences between the polypropylene used in the TVT products as opposed to the polypropylene used

in, say, the Caldera or the Boston Scientific products

that you use, have you?

A. Have I ever done chemical analysis? No, I personally have not done a chemical analysis. Have I read literature regarding chemical analysis? Yes, I've looked at stuff.

Q. My question is, have you ever looked at what the differences, chemical differences are between the polymers used in the TVT products that you are offering an opinion on versus the Boston Scientific or Caldera products that you use?

A. They may use different compounds. They may use different agents to kind of put it together. But it's basically the same product.

Q. And what are you basing that on? Is that an opinion that you intend to offer in this case to a reasonable degree of medical certainty that they are basically the same product with regard to the polymer?

A. They are basically the same product, yes.

Q. And what are you basing that on?

A. On the literature, on the clinical side of it all, and in regards to how they are used, in regards to the use and placement of them, then, yeah, it is a very similar product. They are all polypropylene based meshes, and whether they have different additives or different chemicals within them when they

put them together, that may be the case. But the product itself is basically the same.

Q. So it's fair to say that you don't know if the polypropylene -- different polypropylenes between the TVT family of products and the Caldera and the Boston Scientific, you don't know, as you sit here today, if they have different additives or ingredients between the polypropylenes; right?

A. They probably do.

Q. Okay.

A. They probably do.

Q. As you sit here today, you haven't done any kind of an analysis or study other than looking at the medical literature that has enviable results of any differences that those additives or ingredients might have on clinical outcomes; right?

A. Have I done a chemical analysis? I have not done a chemical analysis, but I've read stuff, yes. I've looked over documents in regards to different additives in the different polypropylenes.

Q. What documents have you looked at that describe different additives between the polypropylene?

A. They are in these binders in front of us, and I have looked them over.

Q. As you sit here today, can you name any different additives or ingredients that are in the TVT family of products that are not in the Caldera or Boston Scientific products?

A. Oh, again, I'm terrible with names. There's different peroxidases that are used. There are -- you know, and I haven't looked as in depth outside of these four products.

Q. Have you ever done any bench research on polypropylene products?

A. I have not done bench research.

Q. Have you ever done any lab research on polypropylene products?

A. I have not done lab research.

Q. Have you ever done any kind of pathological analysis on explanted polypropylene meshes?

A. Have I done pathological analysis? I have collaborated with pathologists in regards to explanted mesh in a clinical setting.

Q. Okay. Have you ever published any articles regarding pathological analysis of explanted polypropylene mesh?

A. I personally have not published. I am familiar with the published material, though.

Q. Have you had any education on -- specifically

A. Mostly from reading, yes.

Q. So no -- is it fair to say that you haven't had any formal education on biomaterials; it's just a result of self education or reading?

A. Bio -- like as in instruction on biomaterials? Yeah, at some of those courses they do go into implanted biomaterials.

Q. What courses are you referring to?

A. The courses that I took for education in regards to placement of the mesh products.

Q. So courses from mesh manufacturers?

A. Correct, mesh manufacturers. From fellowship and residency, going back -- yeah, in residency, when sacrocolpopexies were in fashion, I would have mentors and trainers, have some sort of a didactic regarding implanted materials.

Q. Have you ever held yourself out to the public as a biomaterials specialist?

A. Like I said, I've never been employed as a biomaterials specialist, I've never worked as a biomaterials specialist, I've never gone out there and said, hey, I'm a biomaterials specialist, but I am familiar with biomaterials.

Q. Have you ever published opinions that

polypropylene does not degrade in the human body?

A. I have not published opinions on polypropylene.

Q. Have you ever published -- well, I guess I don't need to ask that question then.

Do you consider yourself an expert on the FDA or FDA regulations?

A. I have been, you know, interacting with FDA regulations regarding medicines, regarding medicines and surgical issues. So I do think I'm an expert in regards to how the FDA works and their function, I do think I'm an expert.

Q. Do you have an understanding of what class of medical device the TVT products are?

A. What class of medical device?

Q. Yes.

A. What do you mean by that?

Q. Well, are you aware that there are different regulatory pathways to legally market a medical device in the United States?

A. Yes.

Q. Are you aware that there's a numerical ranking system for those pathways?

A. There's, and I haven't looked at that in a while.

Q. Okay. As you sit here today, do you know the numerical classification for the TVT family of products?

A. Now you're going back. Not offhand, but I've read it recently.

Q. Do you know what the regulatory pathway is for --

A. I'm trying to remember the classifications. I'm going through -- all right. It's not going to -- if it pops into my head, I'll bring it up.

Q. Okay. Do you know the regulatory pathway to legally market a device like the TVT in the United States?

A. I am familiar with that pathway.

Q. What is it? Do you know what it's called?

A. The 510-K.

Q. And do you know what's required, what Ethicon is required to show or demonstrate in order to legally market a device like the TVT in the United States?

A. There's a long list of regulatory things that are involved. I can't list them to you right off the top of my head but I'm happy to provide them to you.

Q. Okay. Do you consider your expert -- strike that.

Do you consider yourself an expert on medical

device warnings?

A. I have been dealing with medical device warnings throughout my entire professional career, so I do think I'm an expert on medical device warnings.

Q. Do you know what risk information medical device companies are required to put in their IFUs?

A. Again, there's a whole list of regulatory

documents that have listed out the -- what is required. Again, I don't know that offhand, but I have the document right here, and I could provided it to you if you would like.

Q. Do you know what industry standards govern warnings on medical devices?

A. The standards? Again, there's a list of standards that are involved with warnings and regulations, and offhand I cannot repeat that list to you off the top of my head, but I'm familiar with it and I can provide it for you, if you like.

Q. As you sit here right now, without looking through anything, can you name any industry standards or FDA standards that govern warnings on medical devices?

A. I don't remember them offhand.

Q. Do you know what departments of a medical device company are involved in creating the warnings

for a medical device?

A. Do I know which departments?

Q. Yes.

A. Again, I don't know which departments. I'm not employed by a medical device company, so I don't know how they structure their departments.

Q. Have you ever read any testimony from Ethicon employees regarding Ethicon's position on what needs to be in an IFU or instructions for use?

A. I have.

Q. And what testimony have you reviewed and relied on for that?

A. Oh, there's a few of them that have been provided to me. Pite something-or-other. Spells his name weird.

Q. Pite Hinoul?

A. That guy.

Q. Okay. Anyone else?

A. There are others in there, but I'm terrible with names. The only reason I can remember Pite is because he spells his name weird.

Q. And do you remember what Ethicon -- strike that.

Do you know what Pite Hinoul's position was regarding what Ethicon needs to put in an IFU?

A. You know, I read that a while ago, and I can pull it up for you, again. I can't repeat verbatim what his testimony was.

Q. Did you have an understanding when you read Dr. Hinoul's testimony that he was actually testifying as the corporate representative for Ethicon and Johnson & Johnson for medical affairs?

A. Again, it's a long testimony. I don't remember his exact role and his exact what he was doing, but again, it's in the documents I can provide for you. I don't remember his exact title and how he

was introduced.

Q. If Dr. Hinoul testified that a surgeon should be able to rely solely on the IFU or instructions for use for a list of the adverse events associated with the product, would you disagree with that statement?

A. I would. I don't think that relying solely on the IFU for -- what was it for, again? You asked.

Q. For a complete list of the adverse events associated with the device.

A. I do not think that that is the source. I think that we as clinicians and as surgeons, we get our information regarding complications from any type of a procedure, we get them mostly from the literature. We get them from going to meetings. We

get them from our societies.

So the bulk of the knowledge regarding complications is going to come from our training, our background, our years of making us into these surgeons.

Q. So you think that Ethicon's designated representative is just wrong on that point?

A. I do think he is wrong on that.

Q. Do you have an understanding of whether or not Dr. Hinoul is still employed with Ethicon or Johnson & Johnson today?

A. I do not know that. The only reason why I can remember him is because of his name. So I don't

know what he's up to these days.

Q. You don't have an understanding one way or the other of whether he is actually a vice president of the company now in charge of medical affairs?

A. I have not kept up on what Pite Hinoul is doing.

Q. Have you ever drafted an IFU or a DFU for a medical device?

A. Have I personally ever written an IFU?

Q. Yes.

A. I have not personally written an IFU.

Q. Have you ever participated in the drafting or

the writing of an IFU or DFU for a medical device?

A. I have not participated in drafting an IFU. However, I am familiar with IFUs and I am familiar with the process in which they are drafted.

Q. And what's the basis of your familiarity with the process for how they are drafted?

A. Just reading some of the documents that I've read over the years on how of kind of the whole medical system works. I can't think of any one offhand, but there are documents that I have looked oar that have discussed how IFUs are made.

Q. Have you ever worked on the warnings for a prescription drug?

A. Have I personally ever worked on putting together warnings for a prescription drug?

Q. Correct.
A. I have not.
Q. Do you agree that physicians should be made aware of all the significant safety risks associated with a product -- with a medical device in the IFU or instructions for use?
A. Say that again.
Q. It's good that you make me say it again.
Would you agree that physicians should be made aware of all the significant safety risks

associated with a medical device in the IFU?
A. Do I agree with -- I think that risks associated with any surgery, I think that that surgeon should be aware of those risks, I do think that surgeons should be aware of risks of a surgery.
Q. That's not my question.
A. Yeah, go back.
Q. My question was, do you agree that physicians should be made aware of all of the significant safety risks associated with a medical device in the IFU or instructions for use?
A. Oh. I don't think that's possible. I don't think it's possible that all risks associated with a procedure are possible to put in an IFU. If you did that, the IFU would kind of look like these notebooks in front of us (indicating). There are common risks associated with all surgeries, and these are commonly

known by all physicians and all surgeons that I don't think are -- need to be in the IFU.

Q. Do you know if your position on that is consistent or inconsistent with the FDA regulations and guidance regarding what should be in an IFU?

A. Well, if all surgical risks associated with any device or procedure were to be placed in the IFU, again, the IFU would look like the phone book. I

think that reasonable risks, I think that unique things might be good to put in the IFU. However, to say that all risks get placed in the IFU is logistically not possible.

Q. But my question was a little different.

My question was, do you know whether or not that position, your position as you just stated, is consistent or inconsistent with the FDA rules and guidance on what needs to be in an IFU?

A. I don't think the FDA says all risks need to be in the IFU.

Q. Do you know if that's true as you sit here today or...

A. I'm pretty sure of that. Otherwise the IFU would look like the phone book.

Q. What standard or guidance are you relying on for that opinion?

A. I'm -- I have read documents on what's required to be placed in the IFU. However, it's, you

know, common sense that you cannot place every risk in an IFU. It's just there's -- anything can happen in a surgery, and if you have to itemize and list every risk, that's pretty extensive.

Q. Do you agree that physicians should be made aware of the unique safety risks associated with a

medical device in the IFU?

A. I think physicians -- oh, in the IFU? I think that where we get our knowledge in regards to risks doesn't come from the IFU. So the IFU, being the source of where we get our understanding and our knowledge to take care of patients' safely, it's not going to come from the IFU. It's going to come from the literature, it's going to come from going to meetings, it's going to come from mentors, it's going to come from our education.

So the IFU as being a source for our knowledge of risks of the surgery, I don't think it comes from the IFU. I don't think the IFU is the thing that we go to to understand the risks of a procedure.

Q. My question was, do you agree or disagree that physicians should be made aware of the unique safety risks associated with a particular medical device in the IFU or instructions for use?

A. I disagree with that.

Q. Okay.

A. Because -- because -- and the reason why I disagree with that is because, like I said, the IFU is not the source for our getting our information regarding risks from procedures.

If you were to place all risks -- again, if you were to place all risks --

Q. My question is specific to unique.

A. Unique risks of the procedure, it's not going to come from the IFU. When we understand our -- how we kind of get our knowledge, we don't get our knowledge from the IFU. We get it from our societies, from our literature search, from our trainings, from our mentors, from our background. It's not going to come from the IFU. Even unique ones and...

Q. So it's your position that in order to be made aware of the unique safety risks associated with a particular medical device, a physician should not be able to rely solely on the IFU, they should have to go and do their own medical literature research and talk to colleagues, is that accurate?

A. To understanding risks of a procedure?

Q. Unique risks of a particular medical device.

A. I don't think it's going to come from the IFU. I think, again, it's going to come from other sources.

Q. And those sources are the medical literature and talking to colleagues; right?

A. Yes. There are a number of sources that are available for us to get our understanding and our

knowledge in regards to unique and general risks of any procedure, and I think academia, I think literature, the big universities, that's our primary source. I do not think it is the IFU. It's not the IFU.

Q. So are you aware of any communication from Ethicon where they told physicians, hey, before you use these TVT devices, you need to go and read medical literature and go to conventions and talk to people so that you can know the unique risks of this product before using it?

A. There's a bunch of communications that are Ethicon communications that are kind of looked over, and some of them -- I don't really hold too much weight on those. Whether or not they are a community or it's just two people's opinion communicating with each other.

And in my clinical practice as a provider, I don't think -- I don't rely on the IFU to find out unique surgical risks, my colleagues don't rely. We rely on our societies. Whether or not Ethicon internal memos at Ethicon say that or don't say that, it's immaterial.

Q. Are you aware of any statement or contraindication in any of the TVT IFUs that informs

the physician that the adverse events or risks listed in the IFU are not a complete listing of risks in the need to consult other sources for a complete listing of risks?

A. It doesn't say that you need to consult a complete list of other lists because nobody really relies -- I wouldn't say nobody, but the IFU is not a reliable source for understanding risks of a procedure from a clinical perspective. The IFU is a document that is inside the packaging of the products that we use, and by the time we even get the IFU the patient is asleep on the table already. So the IFU is not a source of a -- not the primary source of this information. Am I familiar with the IFUs, have I looked over the IFUs, of course.

But as far as risks from a procedure, it's not the IFU that's going to provide me with an understanding in regards to how to best take care of a patient and how to adjust my practice.

Q. You said that the IFU is in every box; correct?

A. Right.

Q. Do you have an understanding of why it's in every box?

A. You know, I don't know that. I don't know

why they put it in every box.

Q. And you said that it's in the box and by the time that it comes out, the patient is already on the operating table.

A. Correct.

Q. Do you have an understanding that a physician prior to using the device for the first time can either get the TVT IFU offline or ask a sales representative for a copy of that IFU?

A. Yes, that is possible.

Q. So you would agree with me that there are other opportunities for a physician to review the IFU prior to doing the procedure other than just getting it out of the box; right?

A. That is correct. So you can access the IFU. You can look it up online. You can ask a rep. There's a number of different ways to get the IFU, but typically the IFU is sealed in the box when you open up the box, then that's where the IFU is.

Q. Do you agree that a manufacturer of a medical device that will be implanted in a woman's body is required to disclose all significant risks to doctors that come with use of the device?

MR. KOOPMANN: Object to form.

THE WITNESS: Can you repeat the question?

BY MR. FAES:

Q. Do you agree that a manufacturer of a medical device that will be implanted in a woman's body is required to disclose all significant risks to doctors that come with the use of that device?

A. Again, I think all risks -- I think risks that are associated with the procedure, I don't think it's going to be supplied by the device manufacturers. I think that the risks are going to be supplied are from our medical societies, from our training, from our ground, from our mentor, from our colleagues, but I don't think that the primary source of understanding risks of a procedure are going to come from the company.

Q. So you would disagree with that statement; correct?

A. Say it one more time, because I know that there's minutia in the words.

Q. Okay. Do you disagree or agree that a manufacturer of a medical device that will be implanted in a woman's body is required to disclose all significant risks to doctors that come with the use of that device?

A. I don't think that's possible, so I would disagree.

Q. Okay. In preparation for your report, did

you read the testimony of Dr. Weiss BERG?

A. Marty wise BERG; right?

Q. Yes.

A. Yes. I remembered a name.

Q. Do you know whether or not when you reviewed that deposition that he was testifying as a designated representative of the company?

A. No, I don't remember what his actual title was.

Q. Okay. So you don't know whether he was --

A. He's like a medical director or researcher or something like that.

MR. KOOPMANN: You've got to wait for him to ask his question.

THE WITNESS: Sorry, sorry, sorry. I'm not used to giving depositions like this.

BY MR. FAES:

Q. You're actually doing pretty good for a first time.

A. I'm not used to this, so I'm looking at this more as conversational, and I have to kind of catch myself.

Q. Your counsel will tell you you won't get out of here faster but answering the questions faster.

I'll just ask more questions.

A. Okay.

Q. Did you have an understanding when you

reviewed Dr. Weiss BERG's testimony that he was actually testifying as a corporate representative, meaning that his testimony was binding on the company?

A. I believe he was -- what I read, he was this -- and keep in mind there was a bunch of different stuff. Under his title was medical director, so I think he testified as a medical director, I'm pretty sure.

Q. Do you remember whether or not in his capacity -- want to start over.

Do you remember whether or not, in his capacity as a designated representative for the company, that Dr. Weiss BERG testified that the warnings in adverse section should include all significant risks and complications related to the TVT?

A. That may have been the case, but that's not -- you know, I need to refer to the document for the specific, what exactly you said, but I would disagree that all risks need to be in the IFU.

Q. Okay. So --

A. I don't think that that's possible. I don't

think that, you know, like I said, to include all risks within the IFU. You know, anything can happen in surgery. And to say all risks need to be in the IFU would be -- it's a logistics -- logistically it's just not possible.

Q. So you as a paid litigation consultant for Ethicon and Johnson & Johnson disagree with the testimony of Ethicon's designated representative on that topic?

MR. KOOPMANN: Object to form.

THE WITNESS: I would disagree with anybody, whether either the Ethicon representative, you know, anybody. To say that all complications need to be included in the IFU, it doesn't matter who you are. I would disagree. It's just not possible.

BY MR. FAES:

Q. Do you find it odd or unusual in any way that Ethicon would hire a litigation expert such as yourself to disagree with the opinions of its own medical directors?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: Do I what?

BY MR. FAES:

Q. Do you find it odd that you have been hired as a litigation consultant by Ethicon and

Johnson & Johnson to disagree with the opinions stated by Ethicon's own medical directors under oath?

A. I've been retained by Ethicon to voice my opinions, and these are my opinions. And whether or not it disagrees with Marty wise BERG or agrees with Marty wise BERG, these are my opinions.

Q. Well, you understand that that's not just the

opinion of Marty wise BERG, the individual; that's the opinion of Ethicon and Johnson & Johnson because he was --

A. Correct.

Q. -- testifying as their designated witness.

A. Correct. So again, we're talking about all complications being in an IFU; correct? In regards to all complications being in an IFU, if that's Marty wise BERG's opinion, that's Marty wise BERG's opinion. My opinion is that that's just not possible.

Q. You understand that it's Ethicon's opinion -- you understand that Ethicon and Johnson & Johnson are a corporation?

A. I understand.

Q. So they have to testify through their designated witnesses; right?

A. Yes, I understand that.

Q. Okay. And you understand that Ethicon and

Johnson & Johnson has testified that the warnings and adverse reactions section should include all significant risks and complications related to the use of the TVT?

MR. KOOPMANN: Object to form.

THE WITNESS: I understand that is what they said.

BY MR. FAES:

Q. Okay.

A. And I also understand I don't share that opinion.

Q. So you disagree with the opinion of Ethicon and Johnson & Johnson in that regard?

MR. KOOPMANN: Object to form.

THE WITNESS: In regards to inclusion of all complications from a surgery to be included in the IFU, it is not a possible kind of scenario.

For any sort of a document to include all complications of a surgery, like I said, anything can happen in a surgery. And to have to itemize and list all complications in a document that's included in the box of the product, you know, every box of a product would look the size of one of these legal boxes on the table. Because if you were to include all risks of a procedure, it's just kind of too many, and there are

even risks that are -- you know, anything can happen in a surgery. Acts of God can happen in a surgery. Earthquakes can happen, power outages can happen, lots of things can happen within a surgery that can -- and you just can't include all of those things within a document that gets sealed within the box of the product.

BY MR. FAES:

Q. Okay, and I don't want to keep going round and round with you on this topic, but you keep changing the answer to all complications. I just want

to make it clear that the testimony was that the warnings and adverse reactions section should include all significant risks and complications related to the use of the TVT, and you disagree with that; right?

A. I disagree.

Q. Okay. Now I'll move on.

Like I said, I just wanted to give you an opportunity because you kept changing it to all risks and I wanted to make it clear it was all significant risks.

A. I understand.

Q. Okay. Do you agree that doctors rely on pharmaceutical companies such as Ethicon to tell them whether or not the products that they manufacture are

safe?

A. Do I what?

Q. Do you agree that doctors rely on device companies such as Ethicon to tell them whether or not the products they manufacture are safe?

A. You know, I can't speak for what other doctors do.

Q. Do you agree that physicians should be made aware of all of the significant design features associated with a medical device in the IFU or instructions for use?

A. Again, I don't think that that's a possible or logistically feasible thing, to place all design

features of a product in the IFU, again, is not possible. And significant clinical design features that impact care and how we use the product are going to be acquired not from the IFU, it's going to be, again, acquired from other sources.

Q. Would you agree with me that if a company does describe design features in its IFU or instructions for use, that information should be truthful and accurate?

A. Do I agree that the information in the IFU should be truthful?

Q. Yes. My question was, when a company does

include information about the design features of a particular device in its IFU or instructions for use, do you agree that the information they include should be truthful and accurate?

A. Let me see if I understand this. What you are saying is that the information in the IFU, should it be truthful? Yes.

Q. And I was specifically asking about design features, but you are saying -- so you are agreeing that any information contained within an IFU or instructions for use should be truthful and accurate; right?

A. Well, I don't think anybody should lie about anything, whether it's in an IFU or in day-to-day life. So if you are asking me is truthful in this

important, yeah, truthful is important. Not lying is important.

Q. Okay.

A. I don't think I understand the question.

Q. Well, you understand that within the TVT IFUs, Ethicon does describe certain design features regarding the TVT and the TVT mesh; right?

A. Yes, there are some design features in the IFU.

Q. Okay. And I'm just simply asking do you

agree with me that any information that Ethicon has chosen to include there about the design features, that that information should be truthful and accurate; right?

A. I do think that truthfulness and accuracy in all of medicine including IFUs is a good thing.

Q. Okay. Would you agree with me that doctors rely on pharmaceutical companies -- strike that.

Would you agree with me that doctors rely on device companies like Ethicon to investigate and test the safety of their products?

A. Again, I can't speak for other doctors.

Q. Do you agree with me -- well, strike that.

Do you rely on pharmaceutical companies such as Ethicon to investigate and test the safety of their products?

A. Say that again. Sorry.

Q. Do you rely on companies such as Ethicon to investigate and test the safety of their products?

A. In regards to safety and testing, I think that there's a collaboration in regards to safety and testing. I think that the collaboration does involve Ethicon. I think the collaboration does involve academe. I think the collaboration does involve our medical society. So I think it's a collaboration

between researchers in the community, researchers in academe, researchers on their own, as well as industry. So I think it's more of a collaborative type of an arrangement as opposed to Ethicon being the only responsible party.

Q. Would you agree that you rely on companies such as Ethicon to investigate and test the safety of their products prior to placing those products on the market?

A. Say that one more time.

Q. Would you agree with me that you rely on companies such as Ethicon to investigate and test the safety of their products prior to placing them on the market?

A. Again, Ethicon is part of it and academe is part of it. It's more of a collaboration with regards to how things get on the market and the safety of these types of procedures. I don't mean to shorten anything, but it's almost 1:00. If anybody wants to

take a break for lunch, I'm up for that.

Q. Works for me.

A. Sorry to suggest that.

(Lunch recess at 12:51 p.m.)

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Las Vegas, Nevada; Monday, August 12, 2019

1:35 P.M.

Afternoon Session

EXAMINATION (CONTINUING)

BY MR. FAES:

Q. All right. Doctor, we're back on the record after a lunch break. Are you ready to proceed?

A. Yes.

Q. Would you agree with me that a primary sources of information about the risks associated with a medical device comes from the company?

A. The primary risk associated with the medical device comes with the company? I think risks associated with a medical device is most likely going to come from, the way I get the knowledge of these risks, is from medical societies, from training, from literature, from going to meetings.

Q. What about -- sorry. Whether you done?

A. Similar to my other answers to your previous

questions.

Q. What about a device that has just been placed on the market; is your answer different for that?

A. Devices that have just been placed on the

market, there needs to be a collaboration between the manufacturer and academe, that kind of makes sure that everything is okay for release.

Q. Would you agree with me that for a new medical device, a device that's been recently placed on the market, that the primary source of information about the risks associated with that device comes from the company?

A. Again, I don't think it will come from the company. I think it will come from a variety of sources. Not solely the company and not just the company.

Q. So what do you believe is the primary source of information about the risks associated with a medical device that's just been placed on the market?

A. In my personal clinical practice I get my information from the AUGS or SUFU or IUKA (phonetic) from medical societies that kind of are out there to help us in regards to understanding complications of procedures.

Q. For a new device that's just been placed on the market?

A. I mean, things do take time, but there does

need to be collaboration between academe and device manufacturers.

Q. You would agree with me that for a device that's newly been placed on the market there may not be significant risk information from a medical society such arrest an AUGS or a SUFU; right?

A. Correct. So AUGS and SUFU are probably a little bit after the device. However, there's collaboration between academe between the institutions that are doing research in regards to safety and efficacy of products.

Q. So for a new medical device where there isn't significant risk information available for medical societies what do you believe is the primary source of information about the risks for that device?

A. Where it's not from academe, from institutions that are outside of the company, I think that there needs to be research from and a collaborative type of an environment. So I think that there needs to be institutional research as well as industry research. So I think that they can work together in order to really figure out what are the risks associated with a device.

Q. So you would agree with me that there needs to be institutional research performed on a device before that device is placed on the market?

A. I think that the research needs to be in

collaborative with academe. So I think that everybody needs to do their due diligence in regards to figuring out what a product is and how to make sure that it's safe and effective.

Q. Right. So you would agree with me that there needs to be sufficient evidence or studies on a medical device to show that it is safe and effective prior to releasing that device on the market; right?

MR. KOOPMANN: Object to form.

THE WITNESS: Generally speaking, the answer is yes, but there are a lot of devices that are out there that are similar to other devices. It's just a change or a tweak or a minor difference in the actual device itself and the research has been done on something that is a similar product. So a lot of times it's building on previous technology and as that technology kind of develops, both need to be kind of addressed.

BY MR. FAES:

Q. Do you agree with me that the medical -- strike that.

Would you agree with me that a medical device company knows more about the design features of a particular device that they have designed and manufactured than the doctors who use them?

A. That the design regarding whose -- so -- say that question again, that the --

Q. Sure. Would you agree with me that the company that designed and manufactured a particular medical device knows more about the design features of that device than the physicians who use it?

A. In regards to the design features of the device, you know, I don't know. In regards to -- let me think about that. I think that the design features of the device in regards to surgeons they should have the same knowledge as the device manufacturer. They should -- the knowledge of the product in which you are implanting, they should have an understanding of what that product is and how to use it.

Q. Okay. So if I understand you correctly, you believe that the surgeons who use a particular medical device should have the same knowledge about the design features of that device that the company who manufactured it has; correct?

A. They should have an understanding of how to clinically use the device in the safe and appropriate way.

Q. And you would agree with me that the -- since -- strike that.

You would agree with me that the company that

designed and manufactured that device is in the best position to communicate to physicians the information they need about the particular design features; right?

A. I think that the source of where we get our information regarding the design features can come from the company, it can come from academe, it can come from our societies. It comes from a lot of different sources.

Q. Would you agree with me that if there's a reasonable association between a medical device and an adverse event, a company must disclose that information?

A. I think that the company is not going to be the disclosing party. I think that when complications do arise from a medical device, that the complications are going to be told to the rest of the surgical community from our institutions.

Q. So do you agree or disagree that if a medical device company knows of a reasonable association between their device and an adverse event, that the company must disclose that information?

MR. KOOPMANN: Object to form.

THE WITNESS: I mean, I think you are asking is it okay for a company -- what are you saying? I'm trying to read into that question.

BY MR. FAES:

Q. Well, I'm just asking you as a general

principle, do you agree or disagree that if a medical device company knows about a reasonable association between their medical device and an adverse event, that the company must disclose the information?

A. So if a company has knowledge about an adverse event in regards to their device, I mean, again, they are part of this community that they are not the only ones that are hearing about it. So if a company hears about it, it's going to be from, I would expect that the community would hear about it prior to the company.

So if you have this device and it's out in the community and it's being used and then you have an adverse event, you report it to your academic institutions, to your societies, then those are the ones that are kind of the institutions that give us the information needed to adjust our clinical care.

Q. Well, you know that sometimes the way that new adverse events and reactions are reported is they are reported directly to the company; right?

A. I mean, they can be.

Q. They can be reported directly to a sales representative that calls on a physician for a

particular device; right?

A. Sure.

Q. They can be reported directly to the FDA; right?

A. Correct.
Q. Have you ever reported an adverse event for any medical device to the FDA?
A. No, not to the FDA.
Q. And so despite the fact that you have --
A. In regards to complications from midurethral slings, it's the complications I've encountered are already known complications, and I don't think it was reportable to the FDA.
Q. Okay. But you would agree with me that in none of the 50-plus instances where you surgically revised complications from pelvic mesh, none of those cases were reported to the FDA?
A. I have not reported those to the FDA.
Q. So it's fair to say that because of that underreporting by physicians like yourself, the FDA may not know the true frequency of those adverse events?
MR. KOOPMANN: Object to form. Foundation.
THE WITNESS: I think that with the body of literature that's out there and the number of studies

that have been done reporting the instances of a known complication to the FDA is -- I don't think that it's all that useful at this point.
I think at this point we kind of know the -- that midurethral slings are safe but they do have an exposure associated with them and that exposure rate

is low.

Do I think that my not reporting the 50 or so cases in the past couple of years? I don't think that makes one difference.

BY MR. FAES:

Q. So you don't think that if physicians similar to yourself don't report complications that they are aware of to the FDA, that the FDA somehow is aware of the true frequency rate?

A. When we talk about complications, there's known complications, there's severe complications, and there's not severe complications, and these are common complications in mesh exposure that is easily treatable, and you just kind of address that complication and you move forward.

Q. Well, let me ask you this:

Do you consider a case where you have to go to the operating room to surgically revise or excise a surgical mesh to be a serious complication?

A. I do not.

Q. Do you know whether or not the FDA considers that to be a serious complication?

A. They may consider it to be a serious complication if they need to return to the operating room. However, it's an easily revisable complication.

Q. Easily revisable for who? For you, the doctor or for --

A. For the patient as well. It's a simple procedure that normally is pretty straightforward. So to revise a vaginal mesh is -- if there's a small mesh exposure, which is typically the case, you can just go in and revise the mesh pretty easily.

Q. Have you ever done any kind of survey or analysis of whether or not the patients that are having to undergo these surgeries that require a return to the operating room consider it to be a simple procedure?

A. Generally speaking, it is my understanding, in my clinical population, it's not -- it's tolerated well.

Q. Based on what? Have you ever done any kind of formal survey or analysis of that?

A. I have not done a study. No, I have not.

Q. Okay.

A. In regards to exposures, it's just part of kind of the healing process.

Q. Well, you would agree with me -- you say it's part of the healing process --

A. Well, you know, yeah, I want to stop there.

Q. So I'm not sure I ever quite got an answer to my question.

A. All right.

Q. Do you agree or disagree that if -- I mean, we talked about it. Do you agree or disagree that if

there's a reasonable association between a medical device and an adverse event that the company becomes aware of, that they must disclose that information to the, you know, physicians who are interested in using the product?

MR. KOOPMANN: Object to form.

THE WITNESS: So if a new complication is out there, I think that, whether or not you are part of the medical society or part of the institution, that there needs to be this collaborative type of approach to how we implement any new technology.

BY MR. FAES:

Q. Do you agree with me that if there's a reasonable association between a medical device and an adverse event, that a company must disclose that

information in the IFU or instructions for use?

MR. KOOPMANN: Object to form.

THE WITNESS: Yeah, again, I don't think that the IFU is the right Avenue to disclose these types of...

BY MR. FAES:

Q. Do you know whether or not there's any guidance from the FDA or elsewhere that says that if there's a reasonable association between a medical device and an adverse event, that the company must disclose that information?

A. There are guidelines out there, yes.

Q. Okay. So would you agree with me that if a company doesn't disclose a reasonable association between their medical device and an adverse event, that the company would be in violation of those guidelines?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: Say that again.

BY MR. FAES:

Q. Would you agree with me that if a company, medical device company becomes aware of a reasonable association between a medical device and an adverse event and doesn't disclose that information in the IFU, that they are not following the guidelines?

MR. KOOPMANN: Same objection.

THE WITNESS: The -- disclosing these within the IFU, I don't think that that's the most effective way to disclose these types of complications. So the IFU does have a section for adverse events, and within reasonable -- within reason, you can put the adverse events in the IFU, but to put all complications associated with a device is a bit much.

So you -- you kind of need to use reason in regards to what you put in the IFU.

BY MR. FAES:

Q. Okay. My question is a little different.

A. I'm not asking about what is the most effective way or the best way or anything like that.

My question is specifically:

If a company becomes -- medical device company becomes aware of a reasonable association between their medical device and an adverse event and the company does not disclose that information in the IFU, would you agree with me that that company is not following, approximately following the guidelines as set forth by the FDA.

MR. KOOPMANN: Object to form.

THE WITNESS: I think that would depend on the complication. I think it's unique to what we're

talking about here. So what are you specifically asking about?

BY MR. FAES:

Q. I'm not asking specifically about anything. I'm asking -- just asking as a general principle, if a medical device company becomes aware of an association between a medical device and an adverse event and the company does not disclose that information in the IFU, do you have an opinion one way or another of whether or not that company is violating the labeling guidelines?

A. I think, as a general -- I don't think I can answer that generally. I think it needs to be unique to what you're talking about.

Q. Would you agree with me that the information a medical device manufacturer includes in an IFU or

instructions for use should have a scientific basis?

A. Repeat. Sorry.

Q. Would you agree with me that the information a medical device manufacturer puts in its IFU or instructions for use should have a scientific basis?

A. Sure, yes.

Q. Would you agree with me that a medical device manufacturer should put the safety of its patients first, even above profits?

A. Yes.

Q. Would you agree with me that a company that makes medical devices like Ethicon and Johnson & Johnson is required to make sure that its products are reasonably safe?

MR. KOOPMANN: Object to form. Foundation.

Go ahead.

THE WITNESS: I think that, again, it goes back to previously answered questions where safety in regards to do medical devices is a collaboration between academe, between clinicians, between our societies, between industry. So it's kind of this collaborative responsibility.

BY MR. FAES:

Q. But do you believe that the company itself has a responsibility to make sure its products are reasonably safe?

MR. KOOPMANN: Object to form.

THE WITNESS: Do I believe a company itself has the responsibility to make sure that its products are reasonably safe? Everything should be reasonably safe.

BY MR. FAES:

Q. Okay. You would agree with me that ultimately the company that manufactures a particular

medical device can decide whether or not they want to continue manufacturing or selling that device; right?

A. That you are asking if a company can stop production of -- yeah, a company does have that ability.

Q. Okay. Do you believe that a company becomes aware that its products are not reasonably safe, that they should stop selling that particular product?

A. With the focus on reasonably safe. If a product is not safe, then it shouldn't be used.

Q. Would you agree with me that if a medical device manufacturer sells two products that do the same thing, that the device manufacturer -- strike that.

Do you have any expertise or background as an engineer?

MR. KOOPMANN: Object to form.

THE WITNESS: As an engineer?

BY MR. FAES:

Q. Uh-huh.

A. I am not an engineer. I've never held myself out to be an engineer.

Q. Okay. Have you ever worked on the design of a medical device?

A. I have personally not worked on any design of

a medical device.

Q. Have you ever -- so you've never been involved in the design of a medical device; right?

A. The upfront design of a device, I have not. I'm familiar with the design process. I am familiar with how things are designed. However, as far as me personally designing a device, I have not designed a device.

Q. And Ethicon has never asked you to consult on the design of any of their mesh devices; right?

A. That is correct.

Q. You've never held yourself out as a biomedical engineer or an expert in biomedical engineering; right?

A. I have never held myself out as a biomedical engineer. However, I am familiar with biomedical engineering background.

Q. You've never held yourself out as a design engineer, have you?

A. I have never sought employment or functioned as a design engineer. However, in regards to the devices that I use, I understand the design that goes

into them.

Q. Are you familiar with any of the industry standards that govern medical device design?

A. I've read some of the articles that are involved in design. I've read some, yes.

Q. Okay. Prior to your work as a litigation consultant for Ethicon and Johnson & Johnson, were you familiar with the industry -- any industry standards that govern medical device design?

A. Yes. When you start -- when you look at some of the FDA articles in regards to how products are brought to market and how they are designed, so I've read stuff from prior to doing this in regards to design, yes, I have.

Q. Are you familiar with any of the regulatory standards that govern medical device design?

A. I have read about the regulatory standards, yes.

Q. Have you read about them prior to being a litigation consultant for Ethicon and Johnson & Johnson?

A. I have reviewed some of the regulatory standards from FDA documents.

Q. Prior to becoming a litigation consultant?

A. Prior to becoming a litigation consultant. So in regards to the regulatory component, as you kind of go through the process of becoming a clinician, you

get a little bit familiar with some of the products

and the regulations that go along with the products that I use.

But the bulk of that focus has been in regards to patient care, in regards to clinical care, in regards to how this product needs to be used and the patients in front of me.

Q. What are some of the industry standards that govern medical device designs?

A. I don't have them offhand.

Q. What are some of the regulatory standards that govern medical device design; can you name any as you sit here today?

A. Again, the bulk of my knowledge is in regards to -- I know what needs to happen in order to care for my patients. So the actual listing-off of the regulatory standards, I can -- I've read stuff about it, but I can't list those off, but I do know what is required for good, safe patient care.

Q. With regard to design?

A. With regards to the products that I use, with regards to the products and the background of these products.

Q. Are you familiar with any Ethicon internal standards that govern medical device design?

A. You know, those have been provided and I have

looked them over.

Q. Okay. Prior to becoming a litigation consultant for Ethicon and Johnson & Johnson, had you reviewed any of those standards?

A. No, I have not. The Ethicon ones, I have not.

Q. Do you know what a clinical expert report is?

A. Clinical expert report, in context of?

Q. The TVT products.

A. You know, there's a ton of reports. Different reports have different titles. I'm not sure specifically which ones you are referring to.

Q. Do you know what a design history file is?

A. Yes. Design -- DHS, yes, I do. I've looked at those as well. And the clinical expert, I've looked at those as well.

Q. Explain to me what the design history file is?

A. You know, that is the background of what went into design of a product, but it's a -- documents that I have looked over.

Q. Do you know what a DFMEA is?

A. Design -- is that the failure mode -- I forget the acronyms again. Design failure something or other.

Q. Do you know what a purpose of a DFMEA is?
A. It's just to kind of look at the products and figure out what's the safety and how well they work, but I get all those different regulatory forms kind of mixed up.
Q. Have you ever participated in one?
A. I have not.
Q. Do you know what an AFMEA is?
A. It's all in that failure mode kind of list of documents that I have reviewed.
Q. Okay. Have you ever participated in one of those?
A. I have not.
Q. Prior to becoming a litigation consultant for Ethicon and Johnson & Johnson, had you ever reviewed or looked at a design failure mode effects analysis?
A. I did that specifically for this.
Q. So prior to becoming a litigation consultant you had never looked at one; right?
A. I typically do not review those documents, yes, that is correct, I have not.
Q. But have you ever looked at one prior to becoming a litigation consultant for Ethicon or Johnson & Johnson?
A. You know what? I may have, but I'm not sure.

Q. As you sit here today, you can't point to any specific instance where you have reviewed a design failure mode effects analysis prior to becoming a litigation expert for Ethicon and Johnson & Johnson; right?

A. Again, I may have, but I can't recall one specific one.

Q. Have you ever reviewed any of Ethicon's internal standard operating procedures related to design?

A. I believe I have.

Q. Which ones have you reviewed?

A. I can't remember which ones specifically. I have. It's in the documents that I've been provided.

Q. Do you know if you reviewed it for a mechanical cut mesh or laser cut mesh?

A. I think I reviewed for both, but I can't remember specifically which ones are -- I have.

Q. Do you know what the differences are between the Desara sling that you currently use and the TVT sling?

A. I know many of the differences, yes.

Q. Okay. What are some of the differences?

A. Well, the handles are different, how it's placed is different. There are a number of others.

The diameter of the trocars, how the handles are held. But they are basically the same.

Q. Do you know the pore sizes of the Desara mesh versus the TVT mesh?

A. You know, I think Desara is 1.1 or 1.2. They are all above 1 millimeter.

Q. Do you know which one has the bigger pores, the Desara or the TVT sling?

A. You know, when you study pore sizes from all the different -- it becomes difficult. I think the Desara might be a little bigger or a little smaller. I don't remember exactly offhand. No, I don't remember.

Q. Would you agree with me in general that bigger pores in a surgical mesh are a good thing?

A. I think once you get above a threshold it doesn't really matter. I think you need to be a macroporous mesh and if it's a 1.1 millimeter versus a 1.3 millimeter, I don't think that that makes too, too much of a difference, but a macroporous mesh is -- is what I would want.

Q. And what standard are you applying to determine whether or not a mesh is macroporous?

A. The Amid system, Type I Amid, which has a bio of like 75 -- 0.75 millimeters. And then there's

microporous --macro-microporous, microporous, microscopic porous. The four different groups.

Q. Okay. So you would agree with me that the only standard that you are applying for whether or not

a mesh is -- a SUI mesh is Amid porous is the Amid standard; right?

A. I do use the Amid standard.

Q. Are there any other objective standards that you are relying on for your opinion that the TVT mesh is macroporous?

A. There are others out there. However, the literature and what I read and what we talk about at meetings, it's mostly using the Amid system.

Q. What other standards are out there?

A. You know, I don't remember the different ones. The ones I've been kind of looking at are the Amid ones.

Q. So is it fair to say that because you can't remember what the other standards are, the only objective standard that you are relying on for your opinion that the TVT mesh is macroporous is the Amid standard; right?

A. You know, I don't remember offhand, but I'm sure I've read something that involves different standards.

Q. But as you sit here today, you can't remember what those standards are?

A. Yes, I cannot remember offhand.

Q. Is there anywhere in your expert report where it indicates what other standards you are relying on?

A. There is.

Q. Where?

A. Can I grab my report? (Document review.) Where is that section? (Document review.)

On page 4 it talks about the Type I mesh greater than 75 microns.

Q. I could have helped you there. That's what I've been looking at the whole time.

A. You know, I don't think I did put that in there, but, you know, I was wrong. You know, there's other systems other than the Amid system, but the ones I've been working on is just the Amid.

Q. So it's fair to say --

A. Yeah, that's all I put in my report.

Q. Is it fair to say that is the only objective standard you are relying on for your opinions in this case that the TVT is a macroporous mesh?

A. That is what I'm relying on.

Q. Okay. Do you know when the Amid standard came out?

A. I do not know the year offhand.

Q. Are you aware of any other standards that have come out since then, since the Amid standard came out in 1998, that say that the pore sides needs to be greater 75 microns in order for a mesh to be macroporous?

MR. KOOPMANN: Object to form.

THE WITNESS: Typically the ones that I use

is the Amid system, and the literature that I read pretty much uses that. So I know that there are others out there, but I'm not really familiar with it.

BY MR. FAES:

Q. Have you seen in your review of the materials that you reviewed and relied on for issuing your opinions in this case documents from Ethicon engineers who worked on their mesh products giving the opinion that the Amid standard is outdated?

A. I'm pretty much using the Amid system. The other system that's out there, I can't really speak to that.

Q. If someone from Ethicon and Johnson & Johnson were to state that the Amid standard was outdated, would you disagree with that statement?

A. I think the standard is just fine. I think that that's what the literature uses. I think that

that's what most of the societies kind of talk about. I think that that is what's most kind of used in the literature in our society, so...

Q. So it's fair to say that if an engineer or medical director who actually worked on the design of Ethicon's pelvic mesh products stated that the Amid standard was outdated as it relates to a mesh being macroporous, you would disagree with that; right?

A. From a clinical perspective, I think that the Amid standard is fine. This is a mesh that is well

tolerated. There's a lot of knowledge in a lot of studies out there that show that this mesh is fine and that the Amid system, whether you change a classification system or you alter things or devise a new system, the macroporous Type I mesh is the optimal choice for mid-urethral slings, and from a clinical perspective, it works well and it's consistent with what the societies say as well.

Q. Is the Desara sling or the Desara mesh more resistant to deformation than the mesh in the TVT products?

A. More resistant to -- you know, I don't know that offhand.

Q. Are you aware of any literature that says that it is?

A. You know, offhand it's not jumping into my mind.

Q. Are you aware as a current user of the Caldera Desara product that Caldera makes that claim?

A. You know, I don't know what their claims are.

Q. I assume since you aren't aware of that claim, you don't know what the claim is based on; right?

A. Not offhand.

Q. Do you agree or disagree with Caldera that the Desara is more resistant to deformation than the TVT products?

MR. KOOPMANN: Object to form.

THE WITNESS: In regards to -- what do you mean by that?

BY MR. FAES:

Q. Well, assuming that they make the claim that their mesh is more resistant to deformation than the TVT mesh, would you agree or disagree with that statement?

A. You know, I don't know. I'd have to look at what you're talking about, and it's not jumping into my head right now.

Q. When you were using the TVT and TVT-O products, were you using the mechanically cut mesh or

the laser cut mesh?

A. I was using both at different times.

Q. When you were using both at different times, did you find that you had to tension the mesh differently?

A. No.

Q. Are you aware that -- well, strike that.

When you are using the TVT products, did you find that you had to tension the Abbrevo mesh differently than say a TVT-O?

A. The Abbrevo, it's all under tension free. So my actual technique just maintained that it was a tension free kind of a closure.

Q. As you sit here today, as an expert for

Ethicon and Johnson & Johnson on both the TVT-O and the TVT Abbrevo, are you aware of whether or not the IFU or instructions for use actually describes the tensioning technique for those two products differently?

A. They do.

Q. What's the difference between the two tensioning techniques?

A. Well, in regards to -- both of them need to be tension free. So whether the -- how you describe the tension-free closure and in regards to what

technique is recommended, as long as it's a tension-free closure, that's what matters.

There are lots of different surgeons out there that will tension things differently, whether you use a scalpel -- not a scalpel, a hemostat or a scissors or a finger or a dilator. There's a bunch of different ways to tension. As long as it's a tension-free type of a closure, I think that that's adequate.

Q. Well, you would agree with me that the tensioning of any of the TVT devices is important in order for the device to work properly; right?

A. Yes.

Q. If you tension it too loose, it can end up not working and lead to recurrent stress urinary incontinence; right?

A. If it's -- correct. If there's zero tension on it, then it won't be as effective as a properly tensioned, but a properly tensioned DVT needs to be tension free, and -- all these devices.

Q. And a TVT device that's tensioned too loosely and doesn't cure the SUI can potentially lead to a second operative procedure to put in potentially another sling in order to correct the incontinence; right?

A. Yes.

Q. And you would agree with me that if a TVT device is tensioned too tightly, that that tensioning can result in urinary retention or even erosion; right?

A. Too tightly are an erosion? Definitely a urinary retention. If you over tension a sling it will -- if -- I mean, it would have to be pretty tight to get an erosion, but maybe.

Q. If it's tensioned too tightly it could potentially erode into the urethra; right?

A. Correct.

Q. So you would agree with me that it's important for the manufacturer to properly describe the tensioning technique in the IFU or instructions for use; right?

A. No, I would not agree with that. I think that how we learn our technique as surgeons is not

going to come from the IFU. I think that the manner in which a surgeon tensions the TVT is really surgeon dependent. As long as it is a tension-free kind of a closure, then that's all you kind of really need.

Q. So you don't --

A. And how you go about tensioning it, as long as you maintain that tension-free closure, that's

fine.

Q. Do you feel that the person who developed both the device and the procedure, which in this case is Ethicon, has an obligation as part of their design process to research and describe how to properly tension the sling?

A. Say that one more time.

Q. I'll let the court reporter read it back?

(Record read by reporter.)

THE WITNESS: I think that in regards to how we learn as surgeons, I don't think it's going to come from the company. I think that how I learned as a surgeon is going to differ than how everybody else learned as a surgeon, and I don't think that there's a standard technique for tensioning a midurethral sling. I think that that each surgeon kind of needs to find their own technique for tensioning the sling, and I don't think that a -- the device manufacturer is going to tell us how to tension the sling simply because there's so many different ways to go about doing it.

And whatever works for that specific surgeon, as long as it's tension free is fine.

BY MR. FAES:

Q. Do you have an understanding of whether or not that part of the design process, to look at things

like failures from a sling being too loose or urinary retention from a sling being too tight and if you find that those adverse events are occurring too frequently, one of the things they can do to correct that action is to provide proper warnings or instructions in the IFU?

A. I don't think the IFU is the source. I think that the surgeon who is implanting the sling needs to figure out how to tension it properly, and I don't think any surgeon would go to an IFU to figure out how to properly tension a sling.

In my case, I was taught by my mentor, who did a gazillion of them before me, and he taught me how to tension the sling and different surgeons will have different techniques and different ways in order how they learn and how they tension the sling. However, as long as it's a tension-free closure, that's all you kind of need.

Q. But my question was, do you have an understanding of whether or not that's part of the design requirements for the TVT, to make corrections to the IFU to reduce the risk of things like

overtensioning or undertensioning to as low as reasonably possible?

A. I understand. I don't think the IFU is going

to be the place where anybody looks to correct that if they are over or undertensioning. I think they kind of need to figure out how to do it to make a tension free closure. I don't think that an IFU is going to be the source for how they get their information on how to tension any of these slings.

Q. My question, though, is do you have an understanding of whether or not that's required by the design process?

A. Whether or not that's required by the design process? I don't know the answer to that one.

Q. Okay. Do you know what the term ALARP or as low as reasonably possible means in relation to the design process?

A. In reference to what? In reference to the tensioning?

Q. The design process of the TVT, not just specific to tensioning.

A. As low as reasonably possible? You know, a lot of the acronyms and the terms kind of escape me, but if you tell me what this is in reference to, I might be able to talk more about it.

Q. I hate to back back into this again, because we spent a lot of time on what slings you use.

25 Currently, what would you say is your sling

of choice for the treatment of stress urinary incontinence?

A. Either a full-length transobturator or a full-length retropubic.

Q. And currently the two that you are using are the Caldera products; right?

A. Yes.

Q. Do you have a preference of one over the other on a retropubic versus an obturator technique or do you use them 50/50 or how do you select which sling for which patient on retropubic versus obturator? There's a lot of questions there.

A. With regards to whether I do retropubic or a transobturator, a lot of times, because I do think they are pretty equivalent in regards to effectiveness and in regards to complications. I've been using a lot of retropubics. Because I go to so many different hospitals it's difficult, because I don't work with the same team every day over and over. So it's easier for me to kind of streamline how I practice. So if I do the same thing at every place, it makes it easier for me to do a procedure at one hospital and then two weeks later do the same procedure back again. So I kind of try to streamline how I practice. So a lot of times I've been doing a lot of the retropubic ones

because I say, this is a great procedure, I do a ton of the retropubic ones.

If there's, you know, if -- because then the O.R. team kind of knows, oh, this is what Wasserman prefers instead of them having to run around each time and ask, "What do you use? Which one do you like?"

Q. So is it fair to say that you use retropubic more often than obturator? Right?

A. Recently, yes.

Q. Okay. Do you have an approximate breakdown of, like, 70 versus 30 or 80 versus 20?

A. I don't.

Q. Prior to --

A. And I will use either of them equally. If I picked transobturator -- my partner, he likes -- he does more transobturators. I think a lot of it is surgeon's preference too. It's how you were trained, what you were trained in, what you really feel comfortable doing.

Q. And just to refresh my memory, you've used the Caldera products since you moved here to Vegas?

A. Correct.

Q. So back when you were in Washington, you were -- what was your sling of choice just prior to moving here?

A. I was using TVTs.
Q. Okay. And so there's -- there were four different TVTs available at that time in 2015; right?
A. Yes.
Q. What was your sling of choice between those four options in 2015 or so before you left for Las Vegas?
A. The bulk of what I was using was the full-length retropubic.
Q. So the TVT Classic or the TVT Exact?
A. TVT Classic.
Q. And when you were using the TVT Classic as your sling of choice, were you using the laser cut mesh or the mechanically cut mesh?
A. I probably was using both.
Q. Okay. So it's fair to say that you don't know one way or the other which one you were using?
A. Not offhand which one and which specific case. I probably was using both.
Q. On page 16 of your report, the top sentence, you state that you have used both laser cut and mechanically cut slings?
A. Yes.
Q. And have not seen a clinically significant difference in the rate of complications following the

A. That is correct.
Q. Is that an opinion that you intend to offer in this case?
A. Yes.
Q. Is that opinion the result of any formal analysis that you've done between mechanically cut slings and laser cut slings?
A. It's been two reasons. One is that in my patient population there has been no difference in complications associated with them, and the literature does support that as well, that there's equivalence between the laser cut versus the mechanically cut. I don't think it makes one difference.
Q. Okay. But with regard to your own clinical practice and what you have seen, you would agree with me that you haven't done any formal analysis of complication rates between a laser cut mesh and mechanically cut mesh?
A. I have not done a formal analysis.
Q. You couldn't, for example, give me a number of how many mechanically cut mesh slings you've done versus laser cut mesh slings; right?
A. I cannot quantify which I have done most. I have done both of them and I find the complication

rates between laser consult and mechanically cut are equivalent. The literature also supports that as well.

Q. In your report on page 4 -- strike that. Before I get into that, do you have an opinion in this case as to whether or not the mesh in the TVT products is heavyweight or lightweight?

A. Lightweight.

Q. Okay. And you state in your expert report that the weight of the TVT mesh is 100 grams per meter squared; right?

A. Yes.

Q. What standard are you relying on for your opinion that the mesh in the TVT products is lightweight?

A. I don't think there's a standard for lightweight versus heavy weight. It's just my impression that it's lightweight after deal with different types of meshes, that it is lightweight, but there's no kind of gold standard for lightweight versus heavy weight mesh. There are some other kind of, you know, weight, like, classifications out there, but it's not really all that validated. It's more that it's not heavier than as opposed to the other ones that are out there.

Q. Okay. It's fair to say, then, that there's no numerical threshold in your mind at which a mesh for SUI such as the TVT would become a heavyweight mesh; right?

A. I mean, I've read different standards, what's

lightweight, microlightweight and heavyweight, and there are numbers associated with it. Like over 140 is heavyweight and less than 20 -- I forget the actual numbers offhand, but in regards to this TVT mesh, I do think this is a lightweight based upon all the other meshes that are out there.

Q. Okay. Are there any other meshes for stress urinary incontinence that you are aware of that are heavier than the TVT mesh?

A. You know, offhand, again, I don't know the numbers for other companies right now, but all the slings that are out there today are lightweight meshes.

Q. But it's fair to say that, as you sit here today, you don't know of a mesh for the treatment of stress urinary incontinence that would be heavier than the TVT mesh at 100 grams per meter squared; right?

A. Again, I don't know the exact numbers for all the meshes that are out right now, but everything that is out right now would be a lightweight mesh.

Q. And as you sit here today, there's no objective standard or number that you can give me to where you would say at that point that the mesh for SUI is too high and would be considered a heavyweight mesh, you can't -- like 120 or 140 or 160? Is there any number that you would use for that?

MR. KOOPMANN: Object to form.

THE WITNESS: You know, I wouldn't use right offhand because there's no body of literature that really would support that. I have seen things when they try to classify over 140 as being heavyweight and then there's standard and lightweight. There are all these non validated kind of systems of what's light and what's heavy, but again, I would consider the TVT and any of the slings that are out on the market now to be lightweight.

BY MR. FAES:

Q. You also state in your expert report that polypropylene was ultimately determined to be the ideal material for use in slings, and then you've got a reference to a Petros article; right?

A. Let's see where you're talking about.

MR. KOOPMANN: What page?

MR. FAES: Same page, 4.

Q. Wish your stuff was double-sided -- double

line like everyone else's report.

MR. KOOPMANN: We'll note your request.

MR. FAES: Okay.

THE WITNESS: Yes, the Petros article, okay. Yes.

BY MR. FAES:

Q. So is that your -- is that going to be one of the opinions you offer in this case, that polypropylene is the ideal material to be used in

slings, or are you just quoting an article or is that one of your opinions?

A. I do feel that polypropylene is the best material for slings.

Q. Okay. And is that any polypropylene or is that specific to Prolene?

A. Any lightweight macroporous polypropylene is an ideal material for slings.

Q. Okay. But you are not offering an opinion in this case that specifically the Prolene polypropylene is the ideal material to be used in the sling?

A. I mean, the Caldera, yes, I'm saying any lightweight macroporous Type I mesh -- Type I polypropylene sling mesh is the ideal for midurethral slings. That is my opinion.

MR. FAES: Mind if we go off the record for

five minutes?

MR. KOOPMANN: No.

(Recess taken.)

BY MR. FAES:

Q. All right. Doctor, we're back on the record after a short break. Are you ready to proceed?

A. Yes.

Q. We talked earlier about how there's a hierarchy of scientific studies in terms of reliability; right?

A. Yes.

Q. What in your mind is the best and most reliable kind of study?

A. Large meta-analysis, Cochran reviews, the level 1 evidence.

Q. Would you agree with me that one of the most reliable types of study is a long-term randomized controlled trial?

A. That's just the design of a study, so as far as designs of studies go, that's a good design.

Q. You would agree with me that a long-term randomized controlled trial would be considered level 1 evidence; right?

A. Well, it depends on the study. It depends on the design of the study. I can't say that all

randomized controlled studies are a level 1.

Q. Okay. In what circumstance would a long-term randomized controlled study not be considered level 1?

A. If there's a flawed study, if there's something wrong with the study. But yes, randomized controlled blinded studies are the -- kind of the ideal type of a study.

Q. You would agree with me that the TVT sling products are intended to remain in the patient permanently; right?

A. Yes.

Q. And permanently would be considered long term; right?

A. Yes.
Q. You would agree with me it's important to look at long-term studies in evaluating the performance of the TVT sling products; right?
A. Not specifically long term. Short term and long term.
Q. You would agree with me that it's important to look at long-term studies in evaluating the safety and efficacy of those products -- right? -- of the TVT products?
A. Long term and short term, yes.
Q. How do you define the phrase long term and

short term as it applies to studies?
A. I mean, a 20-year study is a long-term study. Those are very difficult to do because it's difficult to get follow-up after 20 years. Five-year studies are pretty good.
Q. Okay. So I'm kind of asking you for what -- with regard to the TVT products, how would you define the phrase "long term" as it applies to studies? Is it 5 years? 20 years? 3 years? 10 years?
A. I mean, 20 years is definitely long term as far as -- five years is a decent amount of time.
Q. What does the term "primary endpoint" mean as it relates to scientific studies?
A. Primary endpoint is kind of the goal of the study, what they are trying to kind of figure out.

Q. Is there a single long-term randomized controlled trial of the TVT Exact product with safety as a primary endpoint that you are aware of?

A. Yes, there is.

Q. And what is that study?

A. Oh, that's that European urology one. I forget the authors are, Angiolli, Angio (phonetic), I think I read one.

Q. And that study is specifically to the TVT Exact?

A. I'm pretty sure that's the Exact.

MR. KOOPMANN: You don't need to guess. If it's referenced in your report --

THE WITNESS: It is referenced.

MR. KOOPMANN: Dig it out.

THE WITNESS: Okay. (Document review.)

This one gives us the TVT and the TVT-O. For the Exact, this is TVT and TVT-O. I don't have an exact -- I was confusing it with the -- for the Exact. I don't have the exact one offhand.

BY MR. FAES:

Q. As you sit here today, are you aware of any randomized controlled trial for the TVT Exact with a -- I'm going to strike and restart that because I'm not sure I started the question correctly.

Are you sit here today, are you aware of any long-term randomized controlled trials for the TVT

Exact with the primary endpoint of safety?

A. Exact, nothing comes off of mine. What I was thinking of was this one (indicating) and it was for the TVT and the TVT-O where the primary outcome was -- hold on. Let me read it to you:

"Compare TVT and TVT-O providing a longer follow-up currently appears in literature and the conclusions is both

surgical techniques are safe with similar results objectively cured. Low complication rates even after a five-year follow-up."

That's the one I was thinking of. So I was confusing it with the Exact.

Q. As you sit here today, is there a single long-term randomized controlled trial for the TVT Abbrevo with an endpoint of safety?

A. Again, I was thinking about this one for the TVT and the TVT-O. Nothing is jumping into my head about the Abbrevo or the Exact.

Q. So as you sit here today as an expert for Ethicon and Johnson & Johnson, you are not aware of any long-term randomized controlled trial for the Exact or Abbrevo with safety as a primary endpoint; correct?

A. I'm not sure. However, both of those products are similar to the TVT and the TVT-O, and I would suspect that the safety issues regarding the TVT

and the TVT-O also translate to those two products as well. But I'm not familiar with one specific article that looked at them. But the fact that the TVT and the TVT-O have been looked at in the study, I do think it also applies to those two products too.

Q. Do you know how many long-term randomized

controlled trials there are for the TVT-O product?

A. How many --

Q. Long-term randomized controlled trials for the TVT-O.

A. I don't know that offhand.

Q. That study that you were looking at, what study was that again?

A. The tension-free vaginal tape versus transobturator suburethral tape five-year follow-up of a prospective randomized trial.

Q. I was just looking for the first author on it.

A. Robert Angioli -- Roberto Angioli.

Q. What's the enrollment period for that study?

A. Enrollment period, 60-month follow-up, 52 patients. No, I don't know. I can look it up for you. (Document review.)

Q. They don't always say.

A. I don't know.

Q. What's the year of that study?

A. That was 2010 European of Urology 58, 2010,

pages 671 to 677.

Q. Is it fair to say that nowhere in the Angiolli study does it break down how many of the TVTs and TVT-Os were mechanically cut mesh versus laser cut

mesh; right?

A. It does not look at that.

Q. Okay.

A. But there are studies in there that do look at mechanically cut versus laser cut mesh, and those studies say that they are basically equivalent.

Q. Are you aware of any studies concerning -- strike that.

Are there any studies that you are aware of that have studied long-term pain, meaning pain over six months, after the TVT Exact procedure?

A. You know, nothing is jumping into my head.

Q. Are you aware of any studies concerning the TVT Abbrevo that have actually studied long-term pain, meaning pain over six months?

A. Again, none is jumping into my head. However, the study that does use kind of safety -- you're talking specifically pain? Nothing's jumping into my head.

Q. What about the TVT or TVT-O; are there any studies you are aware of that studied long-term pain defined as pain over six months?

A. I don't think that's the primary objective.

I think that all -- a lot of the studies do look at pain and look at discomfort as -- in the course of the

study, but nothing specific for just pain itself come -- jumps out to me.

Q. Okay.

A. But pain and discomfort is mentioned in a lot of these articles.

Q. Would you agree with me that the majority of studies on the TVT products just track postoperative pain?

A. I think that it tracks postop pain in the immediate postop period of time and some of them do look at pain long term, but nothing jumps out at me right now for which article I can kind of pull up for you.

Q. But you would agree with me that the majority of studies on the TVT products track just the postoperative pain; right?

MR. KOOPMANN: Object to form.

THE WITNESS: It's difficult to do these longer term studies, but yeah, the bulk of them will use a finite period of time and the bulk are immediate postop pain, but there are studies that do take pain into account.

BY MR. FAES:

Q. Are you aware of any studies concerning the TVT Exact product that track long-term dyspareunia?

A. TVT Exact?
Q. Uh-huh.
A. For long-term dyspareunia? You know, I know I've read something on it, but it's not -- not necessarily from the TVT Exact. I can't remember if it's TVT versus TVT Exact versus TVT-O, but I have read something on long-term dyspareunia.
Q. With which device?
A. I don't remember offhand.
Q. Okay. It's fair to say as you sit here today you are not aware of any studies that have tracked long-term dyspareunia with the TVT Exact?
A. Nothing is jumping out at me right now specifically for the TVT Exact I can't pull up that article right offhand.
Q. Are you aware of any studies concerning the TVT Abbrevo that have tracked long-term dyspareunia?
A. Again, nothing is jumping, offhand, versus the Abbrevo or the Exact.
Q. Are you aware of any studies --
A. But again, a lot of the studies, that it applies to the TVT and the TVT-O, which have been looked at. I do feel it also applies to the Exact and the Abbrevo.
Q. Let's get to those two.

Are you aware of any studies that have actually tracked long-term dyspareunia with the TVT-O?

A. There are studies out there and I have read them and -- yes.

Q. What studies are those that have actually tracked long-term dyspareunia with the TVT-O?

A. For long term, it is -- let me take a look. (Document review.)

I can't remember which study exactly it is, but I have read something. I don't remember the exact term that they looked at, how long they looked at, specifically dyspareunia for long term -- nothing right now. I can't pull it up right now, but I'm pretty sure I read something about that.

Q. But as you sit here today, you can't name or reference -- let me get the whole question out.

As you sit here today, you can't name or reference any specific study that tracked long-term dyspareunia with the TVT-O; correct?

A. Hold on. (Document review.)

With dyspareunia as the primary objective, it's not jumping out at me right now, but I have read something. (Document review.)

You know, it will come to me.

Q. Are there any studies you are aware of that

actually track long-term dyspareunia with the TVT retropubic device?

A. Again, it will come to me. I've read stuff, but I'm trying to remember what exactly it was. But right now it's just not jumping into my head.

Q. Are there any long-term randomized controlled trials designed to look at the rate of chronic pain following the implantation of the TVT Exact?

A. Hold on one second. (Document review.) So there's a Ford article about midurethral sling operations that does mention dyspareunia and a Meagan Shimp article sling from 2014.

In regards to dyspareunia, the surgery itself can contribute to dyspareunia. So all surgeries can contribute to pain, not necessarily the sling itself, but I'm trying to figure out the articles that I referenced. They all kind of blend together.

Q. So you mentioned the Ford article and the Shimp article.

A. Yeah.

Q. So it's your testimony that the Ford article actually tracks long-term dyspareunia, meaning dyspareunia that lasts more than six months, as an endpoint of the study?

A. I think that one is the 24-month one. I

think that one is the 24-month one.

Q. And the Shimp study that one tracks long-term dyspareunia lasting longer than six months as an endpoint?

A. The exact amount of time that they tracked doesn't come to me offhand.

Q. Okay. Other than those two studies, are you aware of any studies on the TVT or TVT-O that tracked long-term dyspareunia?

A. You know, like I said, I'm trying to pull these out of my head, and I'm struggling a little bit for stuff to -- which specific articles to reference, but I know I read it.

Q. Did you do an analysis of these studies in preparing your opinions in this case?

A. I have read it over, not specifically for today, so it's been over time, it's been a while since I looked at them.

Q. Do you know what the conclusions of those studies were with regard to long-term dyspareunia?

A. I mean, I can read my report to you, if you like. In my report I say pain and dyspareunia are reported to occur commonly with at least 40 percent of women reporting dyspareunia and/or pelvic pain, at least 20 percent reporting chronic dyspareunia,

chronic pelvic pain. Pelvic pain is common. I'm going to kind of skim it for you. This is on page 11. Rates of dyspareunia for chronic pain with midurethral

slings like TVT, TVT Exact, TVT-O, and TVT Abbrevo are low. 2015 Cochran review reported that the rates of superficial and deep dyspareunia were low at a 24-month follow-up and sexual function significantly improved from baseline scores," and that was from that Ford article.

The 2015 SGS symptomatic review noted that rates of dyspareunia with retropubic midurethral slings like the TVT and TVT Exact is zero percent, the transobturator slings, like the TVT-O and the TVT Abbrevo, it is 0.16 percent, and that's that Shimp article.

Tommaselli reported in a systematic review and meta-analysis in 2015 that only 13 out of 3,974 retropubic midurethral sling recipients, that's a 0.3 percent and 30 out of 2,432, that's a 1.2 percent transobturator sling recipients reported persistent or chronic pain. Surgical revision for midurethral slings for dyspareunia or vaginal pain are rare occurring in 0.2 percent of patients according to case-control study involving 3,307 patients by Unger and colleagues, and that's 42. "Furthermore, all

surgical treatments for SUI, including pubovaginal slings and Burch colpo-suspensions can cause dyspareunia. In fact, those dyspareunia rates are higher.

Q. What page were you reading from there?

A. 11.

Q. Are you aware of -- strike that.

The TVT Abbrevo, are you familiar that during development, that that particular device was referred to as a mini me?

A. A mini me?

Q. Uh-huh.

A. No. What do you mean by that?

Q. Well, I'm just wondering if you are aware during development that that was a name that was used internally before the TVT Abbrevo name was selected?

A. Who used that name?

Q. Ethicon and Johnson & Johnson.

A. So what did they say?

MR. KOOPMANN: Just answer his questions.

THE WITNESS: No. Sorry about that. No.

BY MR. FAES:

Q. Would you agree with me that the TVT Abbrevo is a mini sling?

A. The TVT Abbrevo is a mini sling?

Q. Uh-huh.

A. I don't think of it as a mini sling.

Q. Okay. But you would agree with me that it's not a full-length sling; right?

A. It's 12 centimeters and it does cover the course of -- I would not consider it a mini sling because it's -- you pass the trocar out similar to the

TVT-O. It's a little bit shorter in that the tails are a little bit on the shorter side, but it is -- it passes through the bulk of the area.

Q. You would agree with me that all of the other full-length midurethral slings on the market are between 40 and 45 centimeters long; is that correct?

A. Yes.

Q. Do you know how long the TVT Abbrevo sling is?

A. 12.

Q. So, in your mind, what is a mini sling?

A. You know, I don't think that there's a standard what's a mini sling, what's not a mini sling. I don't know if that's a standardized term. For me, the mini-slings are the single-incision slings, and that I do think is different than the Abbrevo, whereas the -- whereas the Abbrevo is more like the TVT-O.

Q. So in your mind a mini sling has less to do

with the length and has to do with the fact that the sling is single incision as opposed to a multi-incision?

A. You know, even the term "mini sling," I don't know exactly what that means and what they are referring to, what constitutes as mini versus non mini, but I would consider the Abbrevo like a full length, it does not get cut at the skin level, but it does course through the entire area.

Q. Would you consider the TVT-Secur device to be a mini sling?

A. Yes -- well, again, I don't know what -- I'm kind of making that up, so I don't know what defines mini sling versus non mini sling. In my own personal mind, I would consider a -- because a mini sling to be a single incision, but I don't think that that's standardized. I think that's more personal to me.

Q. You would agree with me that you are not applying any objective standard, then, for determining what is a mini sling versus what is a full-length sling?

A. A full-length sling is a sling that you kind of cut at the skin level. So that goes the entire course from the vaginal incision to the skin level.

The Abbrevo does not go all the way to the

skin level, so I don't know if I would use the term mini, but it does not course the entire length of -- to the actual exit point of the trocar. I would say it doesn't go to the exit point. Whether or not you call it mini or not, I don't know what that -- what mini really means.

And in regards to the single incision, you know, like I said, I just kind of made it up. I would call that a mini sling, but I don't know what mini really means.

Q. Do you know how long the TVT-S device is, the

mesh in that device?

A. TVT-S?

Q. TVT-Secur.

A. TVT-Secur, I think that's 4 centimeters. I don't know. It's short. I don't know that offhand.

Q. Are you applying any objective standard with regard to the length of the mesh in the sling when you decide whether it's a full-length versus a mini sling?

A. I'm just kind of in my own mind saying that -- what I'm kind of dancing around is the term mini. It doesn't really -- it's not that descriptive. I don't know -- one person's mini may not be another person's mini. I don't really like that term all that much.

So the TVT and the TVT-O are placed through the vagina and then they are exited from the vagina to the skin, the entire course of the needle track.

The Abbrevo doesn't go -- the mesh does not lay along the entire track of the needle passer and the Secur only is suburethral.

Q. Let me ask you this:

Do you intend to offer an opinion in this case to a reasonable degree of medical certainty that the TVT Abbrevo is not a mini sling?

A. I don't consider it a mini sling, whatever mini may be. I do classify it in conjunction with the full-length slings. I think that they are pretty

similar.

Q. So is the answer to my question yes?

MR. KOOPMANN: Object to form.

THE WITNESS: So I wouldn't answer to what a definition of a mini sling is. I don't really know what that is.

BY MR. FAES:

Q. So it's fair to say that you don't intend to offer any opinions in this case to a reasonable degree of medical certainty as to what a mini sling is or isn't; right?

MR. KOOPMANN: Object to form.

THE WITNESS: I wouldn't call anything mini. I wouldn't use that term.

BY MR. FAES:

Q. Have you ever heard the single incision slings referred to as mini-slings?

A. You know, I don't know if I've seen it in literature or just kind of how I talk to friends or colleagues, but you know, in my own personal mind, I'm only speaking for me, I'd say the single -- I would use the term mini sling for a single incision, but it's not a -- under this type of environment where we're actually at a deposition, I wouldn't really like to use that term at all.

Q. You understand that a number of single-incision slings were taken off the market;

right?

A. I do.

Q. What's your understanding of why is a number of the single-incision slings were taken off the market?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: Again, I didn't review everything for that. They just didn't work as well. They weren't as effective.

BY MR. FAES:

Q. Okay. And does that include the TVT-Secur device that was taken off the market?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: Again, I did not do a literature search on that, but it just -- the TVTs, the TVT-Os, all the ones that we're talking about today, they worked really well and they still work really well, and it is the technical aspect of placing these slings is actually a pretty simple, straightforward procedure, and when they cannot -- with the single-incision slings they tried to make a technically simple procedure even, you know, smaller, and I didn't really -- and it's not as -- and it wasn't as effective as the other ones. So I...

BY MR. FAES:

Q. And you understand that the mesh that was

used in the discontinued TVT-Secur device is the same mesh that's used in the TVT Abbrevo and TVT Exact; right?

A. Yeah, so I don't think it was a question of the mesh. I think it was a question of how much of a tail you needed, and I think it didn't work, not because of the qualities of the mesh. The regular TVT -- the other products work really well.

Q. Do you have an understanding that the TVT S mesh was 8 centimeters in length versus 12 centimeters for the Abbrevo?

A. That may be the case.

Q. So you agree with me that the -- assuming that to be true, that the Abbrevo was only 4 centimeters in length longer than the Secur; right?

A. Yes.

Q. And as you said, one of the reasons that the Secur didn't work as well was because the tail wasn't as long; right?

A. You know, I don't know. That was a long time ago, and I don't remember exactly what happened with the TVT-Secur and why they were -- so I was kind of guessing as to why they pulled them. So I don't know if it was the actual single incision component, whether it was the actual length of the sling. I do know that the TVT Abbrevo works. I do know that the TVT-O works. I do know that the retropubic TVT and

the TVT Exact work, they all work really well, and they have an excellent efficacy rate, and when I kind of think about these procedures, I mean, all day, we've been here all day today, we've been talking about complications and problems associated with these TVTs, the other aspect is all these women out here

especially in this community here that are no longer incontinent and are very, very happy and that's the vast majority of all the people that are getting these devices and in regard to the TVT-Secur, that was a long time ago and I don't remember the Exact kind of what happened and how everything went down with that.

Q. I think you testified earlier that you ultimately stopped using the Secur after a few cases because you felt it didn't work as well; right?

A. It didn't work as well for me and my -- I'm thinking back, and I did a couple of them, and for me and my hands personally, I've done so many TVTs and TVT-Os and I felt that the procedure itself was very straightforward and had minimal complications, and then they started adding the TVT-Secur. I'm going I don't really get why this is any easier than or less morbid than the traditional TVT and the TVT-Os.

So it was like why do I want to adopt this into my -- where -- and then you start going to the meetings and you go it doesn't quite work as well and you are thinking if it doesn't work as effectively why

would I do a procedure that's just not as effective.

Q. And you would agree with me that you are not offering any opinions in this case or in this place that the TVT-Secur device is safe and effective;

right?

A. You know, I have not been asked to review any of that.

Q. You would agree with me that you -- strike that. I lost my train of thought.

You would agree with me that you are not offering any opinions in this case as to the design of the TVT-Secur device; right?

A. I'm not -- we're not talking about the TVT-Secur today.

Q. Would you agree with me that a shorter mesh or a device for stress urinary incontinence with a shorter mesh has increased tension?

A. You know, I don't know.

Q. Would you agree with me that a shorter mesh for the treatment of stress urinary incontinence is stiffer?

A. You know, again, that was so long ago with those TVT-Securs, and my experience with them is definitely limited and I'm not prepared today to really talk too much about -- talk about it.

Q. Do you know whether or not there are different additives in the Prolene mesh that's in the

TVT versus the Prolene suture?

A. I believe there are, yes.

Q. What additives do you believe are different --

A. I think it's --

Q. Let me get the whole question out.

A. Sorry, sorry.

Q. What additives are different or do you believe are different in the TVT mesh versus the Prolene suture?

A. It's the peroxidases that were -- peroxide, peroxidases were added. Actually, I think they are the same. You know, I don't remember offhand. I'm just -- I'm kind of like you, I'm losing my train of thought too.

Q. Do you know how many more times -- how many more materials are in the mesh than a suture?

A. You know, I'm blanking right now. The after-lunch kind of slowing my brain down.

Q. I understand.

A. Yes.

Q. On page 13 of your report, you state that the TVT, TVT Exact, TVT-O, and TVT Abbrevo devices are made of polypropylene, a material used in surgery for approximately 50 years which was approved by the FDA as safe and effective, and you've got a footnote to that; right?

A. I do.
Q. And footnote 53 is the Librojo affidavit; right?
A. Yes.
Q. What's the Librojo affidavit?
A. You know, I prepared this in March, and again I'm kind of blanking on that one. It's in here. (Document review.)
Q. Oh, you've got a key to the...
A. Yeah. It's not keyed to these numbers.
Q. I know what the Librojo affidavit is, but it looks like you need to refresh your memory.
A. All righty. Okay. Got it.
So Librojo affidavit is an affidavit by Renaldo Librojo, who was a senior director of regulatory affairs and wound closure at Gynecare platform, Ethicon.
Q. So he's an Ethicon employee; right?
A. Yes.
Q. So the Librojo affidavit isn't an affidavit from anyone at the FDA or who works at the FDA. It's basically an affidavit by someone who works for Ethicon and Johnson & Johnson?
A. That is correct.
Q. Other than this affidavit from an Ethicon

employee, are you relying on anything else for your opinion on the paragraph that we just read that the TVT devices are made from Prolene polypropylene, a material used in surgery for approximately 50 years which was approved by the FDA as safe and effective?

A. It is Prolene polypropylene that the sling is made out of.

Q. Okay. But are you relying on anything other than this affidavit which is basically a statement from an Ethicon employee, not the FDA --

A. Right.

Q. -- that the FDA approved the Prolene as safety and effective?

A. I mean, it's been -- it's my understanding that the midurethral sling was made out of a poly -- is a Prolene polypropylene material.

Q. I'm not asking what your understanding of what it's made of. I'm asking you are you relying on anything other than this Librojo affidavit for the statement that the material was approved by the FDA as safe and effective. What else are you relying on, if anything?

A. I'm trying to think. Nothing is coming offhand that -- describing Prolene polypropylene, but I do believe it is Prolene polypropylene, but nothing

is jumping out right now.

Q. I may have already asked this. I don't remember. I apologize if I did.

Do you know how many more times -- strike that.

Do you know how much more material is in a TVT mesh as opposed to a polypropylene suture?

MR. KOOPMANN: Objection asked and answered.

BY MR. FAES:

Q. Prolene suture?

A. You know I don't know offhand. I can't list the different components.

Q. Barry said I did asked and answered it, so I'll rely on Barry.

MR. KOOPMANN: You can.

BY MR. FAES:

Q. You know that Ethicon and Johnson & Johnson sells Prolene sutures --

A. Yes.

Q. -- in the same diameter as what's used in the TVT device; right?

A. In regards to the diameter of the device?

Q. Yes.

A. I haven't looked at how thick the Prolene sutures, how small they get, but I would assume, yes.

Q. Do you know how thick the fibers in the TVT mesh are?

A. Offhand, so many numbers today, I have it right here. (Document review.)

Q. It's 6 millimeters. I'll help you out. I'm not trying to be controversial. Barry can correct me if I'm wrong?

MR. KOOPMANN: The fiber diameter? 6 millimeters? Can't be millimeters.

THE WITNESS: Can't be. That's half a centimeter.

MR. FAES: 6 mill. It might be microns.

THE WITNESS: Six microns is pretty small.

BY MR. FAES:

Q. But like threads. I don't know if you have ever seen one.

A. They are.

Q. Do you know how many sutures it would take 6 mil sutures it would take to make up one TVT device?

A. Not offhand, no, I do not.

Q. Would you agree that more material, more Prolene material could lead to more foreign body reaction?

A. No, I don't.

Q. So you don't agree that the more mesh

material that's in a person's body, the more foreign body reaction there's?

A. I mean, what do you mean? In reference to -- let me think. In reference to what? Like what do you

mean?

Q. In reference to the Prolene polypropylene material.

A. From a clinical perspective, the amount of mesh that's used in a TVT and a TVT-O is not an excessive amount of mesh, and I don't really -- I mean, I don't know how to quantify the foreign body reaction you are kind of talking about. What exactly are you referencing?

Q. I'm not asking about whether you think it's an excessive amount or anything like that.

A. Right.

Q. I'm not trying to be controversial. I'm simply asking would you agree that the more polypropylene -- well, strike that. I'll be specific to TVT.

Would you agree with me that the more Prolene material that's placed in the body, the more foreign body reaction there would be?

MR. KOOPMANN: Object to form.

THE WITNESS: I think that the Prolene is

inert in regards to reactions and it doesn't -- I think it's pretty inert.

BY MR. FAES:

Q. So it's your testimony that the Prolene material doesn't elicit a foreign body reaction?

A. I mean, any sort of material can elicit a

reaction. So if there's -- so I don't know if it's a volume of -- I don't know how to quantity clarify a volume of a foreign body reaction. Either there's kind of a reaction or there isn't. With all devices there's some type of a reaction that normally is transitory and is not clinically relevant.

Q. So do you have an opinion as to whether --

A. As to the volume? I don't think it's a question of volume.

Q. Do you have an opinion as to whether or not the Prolene mesh in the TVT elicits a foreign body reaction or not?

A. The reaction -- I mean, all materials can elicit a reaction. So there's -- normally what happens with that reaction is that there's scarring and it scars in and the reaction goes away.

Q. My question isn't whether or not the Prolene material can --

A. It can elicit -- sorry, sorry.

Q. My question isn't whether or not the Prolene in the TVT can elicit a foreign body reaction. My question is, do you have an opinion as an expert in this case to a reasonable degree of medical certainty as to whether or not the Prolene in the TVT does elicit a foreign body reaction?

A. Elicit a foreign body reaction? A transitory foreign body reaction can take place with the scarring

ingrowth.

Q. And would you agree with me that the more Prolene material that's placed in the body, the more potential there's for foreign body reaction?

MR. KOOPMANN: Object to form.

THE WITNESS: You know, I have to think about -- for me, when I think about a reaction, it's normally a transient temporary reaction that goes away with scarring, and once the healing process is over, the reaction is no longer there. So I never really thought about it as far as volume goes, but it might be related to volume, maybe.

BY MR. FAES:

Q. Do you have an opinion as to whether or not more or additional Prolene material implanted in the human body leads to more inflammation?

A. Probably does.

Q. Do you know when laser cut mesh first became available for the TVT?

A. It was like mid-2000s, 2006, 2007, right around there.

Q. Why did Ethicon start selling laser cut mesh?

A. I think other companies were out there making laser cut mesh and they -- I don't know the exact reason why, but...

Q. Do you know why Ethicon chose not to offer -- well, first of all, do you know whether or not the

Abbrevo is laser cut mesh, mechanically cut mesh or both?

A. It's laser cut.

Q. Do you know whether the TVT Exact mesh is laser cut mesh, mechanically cut mesh, or both?

A. The Exact I think is laser cut or -- I think that one may be both but I think it's laser cut.

Q. Do you know whether the TVT-Secur device is laser cut mesh, mechanically cut mesh, or both?

A. I don't know offhand. That was a long time ago.

Q. Do you know why Ethicon doesn't offer the Abbrevo in mechanically cut mesh?

A. I don't know offhand.

Q. Do you know why Ethicon never -- strike that.

Do you know why Ethicon does not offer the TVT Exact in mechanically cut mesh?

A. Again, I don't know that offhand.

Q. Are you aware of any pelvic mesh product that Ethicon launched after 2006 that used or offered mechanically cut mesh?

A. I mean, the TVT had mechanically and laser cut mesh.

Q. I'm talking about products that were launched after 2006.

MR. KOOPMANN: I think you said launched or offered.

MR. FAES: Okay. Then I'll rephrase the question. Let me re-ask the question, because apparently Barry is keeping track of what I asked here. Thank you Barry. He's been quite the helper today, hasn't he?

Q. You would agree with me that Ethicon has not launched a new pelvic mesh product since 2006 that utilized mechanically cut mesh?

A. You know, I'm not -- nothing jumps out that I can think of, but you know, I don't remember the exact years when they've launched stuff and what's been launched since a certain date.

Q. Do you know why Ethicon continues to offer

the TVT and TVT-O products in mechanically cut mesh?

A. Do I know why they continue to?

Q. Yes.

A. Because they are safe and effective, because they work, because they help with incontinence. I don't understand.

Q. Okay. Do you know why, if those products are safe and effective, why Ethicon wouldn't then offer the Exact or the Abbrevo products in mechanically cut mesh as well?

A. You know, I don't know that, but I do know that between laser cut and mechanically cut mesh they are pretty equivalent, there's -- from a clinical perspective there's no clinical difference between

them, and that's why I think they still offer the mechanically cut TVT, because it's safe and effective and it works and...

Q. Would you agree with me that you have never done any testing on stiffness of mesh yourself?

A. Although I'm familiar with the literature in regards to stiffness of the mesh, I personally have not done testing.

Q. Would you agree with me that the laser cut mesh is stiffer than the mechanically cut mesh?

A. From a clinical perspective I don't think it

really matters. I think that there's kind of a range of stiffness that's required for surgical use of these mesh, and I think that both the mechanically cut and the laser cut fits within that clinical range where it doesn't make a difference whether or not it's mechanical or laser cut.

Q. Have you seen -- have you ever seen the Ethicon study from 2004 concluding that laser cut mesh is three times stiffer than the mechanically cut mesh?

A. You know, I have seen studies in regards to stiffness of the mesh and laser cut versus mechanically cut. However, in a clinical environment in real world practice it doesn't matter.

Q. Do you agree or disagree with the study from Ethicon that found that the laser cut mesh is three times stiffer than the mechanically cut mesh?

A. May be three times. It may be stiffer than the mechanically cut mesh. However, within the clinical environment it doesn't really matter. These slings are intended to be used in a certain way, and in the manner in which they are used, that difference is negligible, it's not important.

Q. We talked about earlier whether or not you were aware of any long-term studies, long term randomized controlled studies with the TVT or TVT

Exact that measured safety as the primary endpoint; correct?

A. Correct, and I was struggling to kind of pull stuff up. It's after lunch, and that safety study that we were talking about earlier, I thought it was for Exact. It was for the TVT and the TVT-O, the Angiolli study that we looked at, but I do think that the conclusions of the study apply to the Exact and the Abbrevo as well.

Q. So you think they apply to the Abbrevo and the Exact even though that study doesn't lay out how many or even if laser cut TVT or TVT-O was used in those studies?

A. Yes, I do.

Q. Are you aware of any randomized controlled trials with a primary endpoint of safety that specifically looked at the TVT retropubic laser cut mesh?

A. That I'm not -- nothing is jumping out as well. I may have read something, but in regards to laser cut versus non laser cut, I do consider both of them equivalent in the clinical setting in how they were intended to be used. So, for me, it doesn't really matter whether it's laser cut or mechanically cut. Both of them work very well, and when they are

used properly, they -- there's no clinical difference between them.

Q. Are you aware of any long-term randomized controlled studies with the primary endpoint of safety that specifically look at the TVT-O laser cut mesh?

A. Again, nothing is jumping out at me, but I think I read something.

Q. Do you agree with me that laser cut mesh has softer or sharper edges than mechanically cut mesh?

MR. KOOPMANN: Object to form.

THE WITNESS: I haven't really thought of it that way because I do think that both of them in the clinical setting are equivalent. So I didn't really think of them in regards to sharpness or softness. I don't really have a way to quantify that.

BY MR. FAES:

Q. Okay. Have you ever looked at or seen photos of comparing mesh edges of laser cut versus mechanically cut mesh?

A. I have seen those.

Q. Okay. And do you recall what the -- that those photos look different?

A. Yes, they do.

Q. Okay. To you, did the laser cut mesh edges appear to have a sharper edge as opposed to a rounded?

A. I was just looking at the pictures, so I couldn't really tell. However, those photos were also not how they were intended to be used. That was excessive force on these slings. In the clinical environment as a surgeon, it doesn't matter if it was laser cut or mechanically cut. Both of them in the clinical environment in the real world, how it was intended to be used, they are both equivalent.

If you take it to the lab and test it in certain ways and it looks differently, that's just in the lab environment. But in the real world it doesn't really matter.

Q. Would you agree that doctors rely on Ethicon to tell them whether or not a mesh is too stiff, their mesh is too stiff?

A. Again, back to previous answers in regards to who is the responsible party for informing physicians, I look to the medical societies and academe to provide me that information.

Q. Would you agree with me that one of the properties of an ideal transvaginal mesh sling is if it wouldn't be too stiff; right?

A. Say that again.

Q. You would agree with me that one of the properties of an ideal transvaginal mesh sling is it

be made of a material that is not too stiff; right?

A. Similar to the polypropylene, yes, like the polypropylene mesh that we use. It's the best treatment option for incontinence and it's safe and effective.

Q. You would agree with me that you would want the mesh to elongate and mimic the natural vaginal tissue; right?

MR. KOOPMANN: Object to form.

THE WITNESS: Elongate and mimic the natural vaginal tissue? I don't understand what you mean by that.

BY MR. FAES:

Q. So do you have an opinion of whether or not you would want the mesh in the TVT to elongate and mimic the natural vaginal tissue or is that not something you would want to occur?

A. I have no idea what you mean by elongate and mimic. What do you mean by mimicking the natural vaginal tissue? Can you give me an example?

Q. You would agree that you would want the mesh to be soft and compliant with the natural vaginal tissue; right?

A. Yes.

Q. And if a mesh was soft and compliant, it

would mimic the natural vaginal tissue; right?

A. So elongate and mimic the natural vaginal -- I don't know exactly what you mean, but in regards to the sling, you would want it to be not like a rigid board, but you also don't want it to be Jello either. So you have to have some integrity to the mesh in order to provide anti incontinence or its effectiveness, but you also don't want it to be stiff like a board where it's not compliant.

Q. Right. You would agree with me is that if a mesh is stiff like a board and not soft and compliant, that increased stiffness can be associated with complications; right?

MR. KOOPMANN: Object to form.

THE WITNESS: For instance, let me give you an example, would I want a midurethral sling to be made out of cement or a metal band? No. You want some flexibility with it, so you need some strength to it as well as some flexibility to it.

BY MR. FAES:

Q. So you would agree with me that if a mesh were too stiff, there could be increased complications associated with is that increased stiffness; right?

MR. KOOPMANN: Object to form.

THE WITNESS: Sure.

BY MR. FAES:
Q. Okay. What kind of complications could be associated with a mesh that is too stiff?
A. You know, I don't know offhand because I haven't worked with mesh that is too stiff.
Q. Would you agree with me that meshes with a higher stiffness or that's too stiff could cause increased tissue erosions?
MR. KOOPMANN: Object to form.
THE WITNESS: Like which mesh? I don't know -- this is like hypotheticals, and you are kind of bringing up, hey, if it was like -- but I'm trying to figure out exactly what you are talking about, and that's kind of where I'm getting lost.
BY MR. FAES:
Q. Well, I'm talking about -- I'm asking a hypothetical but -- so first of all, you are saying that you are not aware of any mesh anywhere that would be too stiff for the treatment of stress urinary incontinence?
A. Well, I mean, they've used different products in the past that have not been compliant -- so there were some stiff ones out there prior to -- I'm just trying to think in the past, but yeah, so...
Q. Maybe the Trelex mesh, maybe you are familiar

with that product?
A. It was before that time. Yeah, all of those were before my time.
Q. All right. So I'm not trying to be --
A. Yes.
Q. -- here. I'm just asking simply --
A. Yes, yes.
MR. KOOPMANN: Stop saying yes.
THE WITNESS: Okay.
BY MR. FAES:
Q. You would agree with me that a mesh used for stress urinary incontinence that's too stiff could increase tissue erosions; right?
MR. KOOPMANN: Object to form.
THE WITNESS: So I don't know the answer to that. I don't know the answer to that. So in regards to erosion, I have not read anything about different meshes. The focus that I've been kind of focused on is the polypropylene mesh. Back before, back in the day I don't know exactly what they were using, so I'm kind of guessing at things.
BY MR. FAES:
Q. Okay. So you don't have an understanding of any -- that there used to be certain meshes that were used for stress urinary incontinence that are no

longer used because they are too stiff or had other problems; right?

A. That was definitely before my time, but there definitely are.

Q. Other than perchance the percent lean mesh which isn't a polypropylene mesh; right?

A. Correct. I'm getting a little bit loopy here too.

Q. Do you want to take the last five-minute break?

A. Yes, I need coffee.

(Recess taken.)

BY MR. FAES:

Q. We're back on the record after a short break. Are you ready to proceed?

A. Yes.

Q. Would you agree with me that the more flexible a mesh is, the less likely potential it has for complications?

A. I don't think that. I think you need to have a right balance between flexibility and resistance in order to have -- be a good mesh. I don't think that a completely flexible mesh -- let's say you took something like a rubber band and used that for a mesh, which is very flexy. I don't think you would get

complications with a rubber band.

Q. So assuming that this hypothetical mesh is

sufficient to do the job --

A. Right.

Q. -- you would want the most flexible mesh that you can get that's sufficient to do the job of treating the stress urinary incontinence; right?

A. So in regards to flexibility, I think that you need to have some resistance and some compliance. I don't know the exact balance between those two. And complications in regards to flexibility and the -- I don't think that if it's completely flexible you are not going to be complication free.

Q. Right. And I'm not asking if a mesh is less flexible if you are going to be complication free. I'm just asking do you agree or disagree that in general the more flexible a mesh is, assuming it's sufficient to do the job, the less likely potential it has for complications?

MR. KOOPMANN: Object to form.

THE WITNESS: I don't know the answer to that, because I haven't encountered that or read that or in my experience, you know, we've been talking about kind of these hypotheticals and it's difficult for me to answer what I think is going to happen in

the hypothetical situation and it's kind of hypothetical. I don't know exactly what you are talking about.

But in regards to stiffness versus

flexibility, I think there needs to be a balance between the two.

BY MR. FAES:

Q. Would you agree with me that mesh can cause pain for women who have it implanted?

A. I think any surgery can cause pain. I don't think that is something unique to midurethral slings or mesh. I think that all surgery there's some pain and discomfort associated with it.

Q. Right but I'm not asking about the procedure. My question is specific to mesh.

Do you agree or disagree that mesh can be the cause of pain for a woman that has it implanted?

A. I do not think that mesh itself causes pain.

Q. Would you agree that the inflammatory reaction and foreign body reaction of the mesh can cause pain for the women that have it implanted?

A. I think that the procedure itself has -- if you took a scalpel on a skin you would have an inflammatory reaction. I think that all procedures cause pain and discomfort and inflammation which is

usually transitory, that goes away pretty quickly. Well, there's pain with all surgery, and I don't think that this is something that is unique to TVTs or mesh.

Q. I'm not asking you about the incision from the mesh or anything like that. My question is, do you agree or disagree that the inflammatory reaction

and chronic foreign body response from a mesh can cause pain in women who have it implanted?

MR. KOOPMANN: Object to form.

THE WITNESS: I don't.

BY MR. FAES:

Q. Okay. Do you agree that a mesh erosion or exposure can cause pain for women that has it?

A. Typically the erosions that get presented to me aren't presented from -- the presenting factor isn't pain. Sometimes partners do feel some discomfort with intercourse, but the typical presentation for a mesh exposure is, you know, I kind of feel something there, what is that? So I wouldn't say that all mesh exposures are associated with pain.

Q. I understand that they are not all associated with pain, but my question is specific.

Would you agree that a mesh erosion or exposure can cause pain for a woman who has it?

A. Sure.

Q. Would you agree with me that a mesh erosion or exposure can cause dyspareunia for a woman who has it?

A. A mesh -- I don't think -- again, I don't think -- just like the previous question with regards to pain, when I said do all mesh exposures are associated with pain, I don't think all mesh exposures.

Are all mesh exposures associated with dyspareunia? I don't think that either. I understand that wasn't your question, and your question was can an exposure be associated with dyspareunia. A lot of times it's the partners that feel it and they are uncomfortable, but typically in my experience it's not been the patient that actually felt the pain, but sure maybe.

Q. So in response to my question of whether or not an eroded or exposed mesh can cause pain for women that have it, your answer is maybe?

A. It can. It can. There can be pain with intercourse associated with an exposure. That's usually temporary and easily addressed.

Q. Would you agree with me that mesh -- strike that.

Would you agree with me that an eroded or

exposed mesh can cause his-pareunia --

MR. KOOPMANN: Object to form.

BY MR. FAES:

Q. -- for the patient's partner?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes, I will agree on that, but the dyspareunia and the pain on the patient's side is minimal, if any at all.

BY MR. FAES:

Q. Would you agree with me that mesh can cause

chronic or long-term dyspareunia for women who have it?

A. No, I do not. I think in regards to dyspareunia surgery can cause dyspareunia, scarring can cause -- any procedure that happens can cause -- in the vaginal area. Any time you make a incision you can get some dyspareunia. Do I think that the mesh is the cause of the dyspareunia? I do not.

Q. Would you agree that a woman can experience scar plate formation from a mesh implanted in the vagina?

A. I don't think that scar plate formation really exists. I don't really buy into that.

Q. Would you agree that a woman can experience scarring from the mesh following implantation?

A. Yes, with all surgeries there's scarring associated with it.

Q. Would you agree with me that women can experience chronic or long-term dyspareunia from that scarring?

A. With any surgery there can be some pain associated with intercourse. Whether or not you are using a mesh or you are using mesh, there's higher dyspareunia rates associated with Burch procedures, higher dyspareunia rates associated with pubovaginal slings. So I don't think that's something unique to the mesh procedure. I think it's something inherent

in all procedures in the vaginal area.

Q. But you would agree with me that a woman can experience chronic or long-term dyspareunia from scarring that comes from the mesh; right?

MR. KOOPMANN: Object to form.

THE WITNESS: No. I think that it's scarring from surgery, not necessarily from the mesh, because when you look at these dyspareunia rates and you look at the other procedures that have been used in the past in regards to dyspareunia, midurethral slings actually have the lowest dyspareunia rate when you start comparing things out.

So I think it's inherent of surgery, not at

all the mesh.

BY MR. FAES:

Q. Would you agree with me that frayed edges of a mesh can injure a woman's vagina?

A. I don't think that the frayed edges are a factor.

Q. So you believe that if a TVT or other mesh becomes frayed, that that fraying can't injure a woman's vagina?

MR. KOOPMANN: Object to form.

THE WITNESS: Do I think fraying can -- so in regards to frayed edges, I think -- you know, I think that the mesh can have an exposure. I think you can have poor healing. I don't necessarily think that

it's the frayed edge itself. I mean, exposures do happen, and I wouldn't necessarily point the finger at a frayed edge. I would say it's more a part of the healing process. Any time you implant something, if it doesn't heal properly, it may result in a low percentage, it can result in an exposure, but just like a Burch procedure, you can get an exposure too with allograft or a xenograft you can get exposures too. So in regards to the frayed edge specifically, I think it's anything that's implanted can have an exposure.

BY MR. FAES:

Q. So you would agree with me -- well, strike that.

First of all, do you believe that a TVT mesh edge can become frayed?

A. If you pull on a TVT too hard, in non physiologic conditions it can become a little stretched out.

Q. So is it your opinion that the only way that a TVT mesh edge can become frayed is if you pull it too much?

A. In the clinical practice, the way that the sling was actually intended to be used, you should not have edges that are frayed because there's no excessive force on the device. It should scar in nicely.

Q. So you would agree with me that if you took, for example, a TVT or TVT-O mechanically cut mesh out of the box and the edges were frayed before you implanted it in the patient then you wouldn't use that device in a patient and you would get another one?

A. What do you mean by "frayed"?

Q. I mean, that there's frayed rough edges of the mesh that are visible prior to implanting it in the patient.

MR. KOOPMANN: Object to form.

THE WITNESS: I mean, that hasn't happened. The edges of the mechanically cut mesh are -- they are pretty straight across, and I don't think that when placed properly -- I haven't found them to be frayed. I think we're talking about two different things. I think that the fraying that I'm referring to is if you put an excessive amount of force on a non clinical excess force on the sling it can stretch out and become unravelled a little bit, but the ones that come out of the box that are mechanically cut are fine.

BY MR. FAES:

Q. You state in your expert report that you have seen no evidence in your practice or the published literature indicating that particle loss occurs in the body.

You have never reviewed or read any documents from Ethicon indicating that particles can migrate

through the vaginal tissue and cause pain?

A. You know, I've seen some internal documents that referenced that, but that's not what I feel to be the case.

Q. Have you ever encountered a sealed blister or sealed box of TVT or TVT-O that had loose particles floating around in the package before you used it?

A. I don't think I have. Honestly I haven't really looked, but I don't recall seeing anything like that.

Q. If you were to encounter that, would you still go ahead and use the device, or would you consider that fine that there's particles floating around in the box that aren't attached to the mesh?

A. Again, this is kind of a hypothetical type of a situation that you are throwing out there, so I don't know. I don't know.

Q. So you say it's a hypothetical. You've never actually seen internal documents from Ethicon and Johnson & Johnson where sealed blister packs of TVT-O were returned to Ethicon and Johnson & Johnson for precisely that reason, because there were particles in items floating around in the package?

A. I may have glanced over one of that in the review materials that have been provided, but you know, I didn't really pay too much attention to it.

Q. If you were to encounter that situation in

your clinical practice today, would you consider that to be a defect or problem with the mesh or would you just go ahead and use it in your patient and figure it's fine?

MR. KOOPMANN: Object to form.

THE WITNESS: Again, if there's little particles floating around there, would I use it? If the mesh looked okay and if it was intact, yeah, sure.

BY MR. FAES:

Q. Okay. While you state that you have seen no evidence in your practice or published literature indicating that particle loss occurs in the body, would you agree with me that if particle loss is occurring in the package, in the blister package before you even place it in a patient, that that's evidence that the mesh is at least physically degrading?

MR. KOOPMANN: Object to form.

THE WITNESS: No.

BY MR. FAES:

Q. So you don't consider particle loss in a blister package to be evidence of physical degradation of the mesh?

A. I do not, but again, you are throwing out these hypotheticals at me and I'm going, you know, I'm kind of making it up as I go, honestly.

Q. I mean, they are not hypothetical because

they have actually occurred.

A. And I'm kind of guessing about these things and I'm going -- and honestly, I don't really know but

I wouldn't think that anything is degrading.

Q. Okay. What would you need to see in order for you to think that a TVT mesh was physically degrading?

A. What would I need to see in order to think that it's degrading?

Q. I mean, if particles falling off the mesh isn't evidence of degradation to you, what is?

A. I haven't really thought about that. What would I need? Well, so now I'm trying to address a hypothetical with another hypothetical. So if I took the mesh out of the box and I touched the mesh and I crinkled it up and it dissipated, I think that possibly would degrade, but that doesn't happen. I'm just making stuff up.

Q. So hypothetically --

A. I've got an idea. If I got a box and it was packed with a mesh and then I opened it up and the handles were just there and there was no mesh there, that would be degraded. You know, I'm answering these what I think is kind of an off hypothetical question with off hypothetical answers and I'm sorry I'm doing that but it's...

Q. So hypothetically, if you picked up the mesh

and it completely fell apart in your hands, it would

be evidence to you of physical degradation; right?

A. It's a goofy answer because I think it's kind of a goofy question. No offense. I'm sorry. But I'm just kind of making stuff up, and I'm sorry about that.

Q. But just to be clear, just particles falling off of the mesh wouldn't be physical evidence to you of physical degradation?

A. If there were a couple of fibers, no, it would not.

Q. Do you know whether or not Ethicon actually has design and manufacturing specifications that indicate how many particles are acceptable within a package of TVT or TVT-O in order for those products to be sold?

A. I'm sure I've read something along those lines.

Q. As you sit here today, do you know what those standards are?

A. Not offhand.

Q. Are you aware of whether or not the TVT and TVT-O manufacturing line was ever shut down due to excessive particles and foreign material in the packaging?

A. I do not know.

Q. If a TVT or TVT device had excessive foreign material or particles in the product or packaging, would you consider that a potential safety issue?

MR. KOOPMANN: Object to form.

THE WITNESS: No.

BY MR. FAES:

Q. Do you know whether or not Ethicon and Johnson & Johnson considered excessive particles in the package or foreign materials in the product or packaging to be an excessive safety -- or to be a potential safety issue?

A. They may have but I'm not familiar with it. I think it's in there someplace.

Q. Are you familiar with what any of Ethicon's standards are for the amount of foreign material that's allowed in the products or packaging for the TVT or TVT-O?

MR. KOOPMANN: Object to form.

THE WITNESS: No, not offhand.

BY MR. FAES:

Q. You state in your report that you have seen no evidence in your clinical experience indicating that the Prolene mesh used in the TVT products degrades in the body; right?

A. Correct.

Q. Have you ever seen evidence of particle loss from a TVT or TVT-O?
A. No.
Q. Have you ever seen -- strike that.
Have you seen any issue reports or complaints to Ethicon and Johnson & Johnson of frayed edges of the TVT mesh?
A. Say that again.
Q. Have you seen any complaints from customers to Ethicon and Johnson & Johnson of frayed edges of the TVT mesh?
A. I may have in review of these documents, I may have seen something, but I don't remember offhand what was exactly said. Those are one specific e-mail, but I don't remember.
Q. Okay. So if you have seen complaints or reports of that, do you think those complaints are just wrong?
A. You know, I would have to review those again. We're talking kind of this hypothetical about frayed edges and particle loss that I don't really think is clinically relevant.
Q. You state that the -- well, first, starting on page 14 of your report, you have a section entitled "Response to Plaintiff's Experts' Contentions"; right?

A. Yes.

Q. What plaintiff's expert's contentions are you specifically referring to there?

A. You want who wrote those plaintiffs? There's a Margulis one, Rose en swag one, there are others that I've looked at.

Q. Okay. And one of the contentions of experts, of plaintiffs' experts that you disagree with is that the TVT products cause a chronic foreign body reaction; right?

A. Yes.

Q. Have you reviewed the testimony of Dr. David Robinson in formulating your opinions in this case?

A. David Robinson? Again, I'm terrible with names. That one does not ring a bell.

Q. Okay. I'll represent to you that he was a medical director with Ethicon between 2005 and 2010. Were you aware that he testified as the medical director in charge of the TVT products that the TVT mesh will undergo a chronic foreign body reaction for as long as it's implanted in the body?

A. Like I said, that's the opinion of one person. We've talked about that earlier with previous.

Q. Okay.

A. Yeah.

Q. It's the opinion of one person who happened to be the person that Ethicon and Johnson & Johnson

selected to be their medical director for the TVT products; right?

A. That's correct. Actually, you are telling me that's correct. I don't remember David Robinson?

Q. Yes.

A. When I think of David Robinson I think of the guy that used to play for the spurs, but it's definitely not him.

Q. It's fair to say if he made that statement that the TVT will undergo a chronic foreign body reaction for as long as it's implanted in the body, that you disagree with that statement?

A. I don't agree with that.

Q. Do you think that's an important thing for a medical director for the TVT products to know whether or not the mesh in the TVT undergoes a chronic foreign body reaction or not?

MR. KOOPMANN: Object to form.

THE WITNESS: Again, that is one person's opinion in a document that I probably have read but it's not jumping out at me and that is just one person's opinion. It's my opinion that it doesn't.

BY MR. FAES:

Q. It's actually sworn testimony under oath, not a document.

A. Okay.

Q. But --

A. This is my opinion.
Q. Do you believe that Ethicon and Johnson & Johnson made a mistake if they hired a medical director that made this statement that you disagree with?
MR. KOOPMANN: Object to form.
THE WITNESS: I can't speculate about that, that they made a mistake in hiring David Robinson. Is --
BY MR. FAES:
Q. Let me ask a different question.
A. Okay.
Q. Do you believe that -- because you disagree with this statement --
A. Yes.
Q. -- which was made by their medical director, do you believe that Dr. Robinson was incompetent if he doesn't know whether or not the TVT causes a chronic foreign body reaction?
MR. KOOPMANN: Object to form.

THE WITNESS: I don't know anything about David Robinson aside from the Spurs, and I may have looked over his testimony at some point in time in preparation for today, but it is my opinion that it does not have a chronic reaction.
BY MR. FAES:
Q. Okay. One of your other opinions is that

the -- you disagree with plaintiff's contention that the mesh is cytotoxic; right?

A. That is correct.

Q. What is your understanding of what cytotoxicity is?

A. Toxic to cells.

Q. C-e-l-l-s.

A. Yep.

Q. What is your understanding of what happens to human tissue when it's in contact with a cytotoxic substance?

A. Cells can die with cytotoxic substances.

Q. So one of the potential effects of exposure to a cytotoxic substance is tissue necrosis; right?

A. Sure, yes.

Q. And you would agree with me that one of the potential effects of tissue necrosis is that the skin around the substance can die; right?

A. If you -- let's take acid which is cytotoxic, if you put acid on your skin, the cells around the acid are going to die. That would be like a cytotoxic substance. Chemotherapy ask a cytotoxic substance that will kill the cancer cells.

Do I think that something placed around a cytotoxic entity can die, yeah, they can die. However, I don't think this mesh is cytotoxic.

Q. Would you agree or disagree that a mesh

exposure could be evidence of exposure to a cytotoxic substance?

A. I would disagree.

Q. Would you disagree that mesh exposure, including tissue necrosis around the exposed mesh can be evidence of exposure to a cytotoxic substance?

A. Say that again.

Q. Would you agree that tissue necrosis in the area surrounding the exposed mesh could be evidence of exposure to a cytotoxic substance?

A. I don't think that the mesh is cytotoxic. If you put a cytotoxic substance next to the mesh and the skin, it probably would cause necrosis, but it's the cytotoxic substance that you are putting next to the mesh that would cause the necrosis. It's not the mesh that's cytotoxic. It's whatever you are putting next

to the mesh. Is that what you are asking?

Q. Yes.

A. I don't think the mesh is cytotoxic.

Q. I understand that.

A. I got that. Okay.

Q. Are you aware -- strike that.

Have you seen cytotoxicity studies done on the TVT mesh prior to its launch in the United States?

A. So you are talking like 1990s?

Q. Right. I'm talking about 1997, actually, 1996, '97.

A. I think I have, but it's not popping up right now. I have read some of the older stuff, but it's not popping up in my head right now.

Q. Are you aware that the TVT mesh tested moderately are markedly cytotoxic on four separate occasions prior to TVT being launched in the United States?

A. So in regards to previous studies and cytotoxicity, the body of knowledge, the evidence right now in regards to use of a midurethral sling is that it is not cytotoxic.

The previous studies that were done in the past, I'm sure there's lots of studies that looked at -- I'm elaborating too much. I feel that the body

of knowledge in regards to cytotoxicity and the TVT is that it's not cytotoxic.

When you look at this and you say, okay, 99.8 percent or 99.2 percent of the patients do not have an erosion or, you know, very, very low percentage of patients have an erosion, it says to me, hey, it's not cytotoxic.

The erosion I do not feel is a result of cytotoxicity. An erosion has to do with healing, has to do with other issues other than -- not cytotoxicity.

Q. Well, you would agree with me that if the mesh material were cytotoxic, that an erosion could

be -- strike that.

You would agree with me that if a mesh material were implanted that were cytotoxic, a mesh exposure could be a potential result of exposure to that cytotoxic substance; right?

A. I would be guessing. I can't answer. That's a hypothetical that I have no idea. I'm just guessing.

Q. Okay.

A. Earlier I was talking about if you placed a cytotoxic substance next to the mesh it would cause necrosis. Again, on that one I'm guessing too. No

one would place chemotherapy agents intentionally to see if it necrosed vaginal tissue. It's just not done. These are kind of hypothetical situations that I'm making up to say, you know, well, maybe, but the reality is that this is not cytotoxic, this is not what's causing necrosis, this is not causing these erosions.

Q. As an expert for Ethicon and Johnson & Johnson, who is giving the opinion that the mesh is not cytotoxic, how do you explain the four separate tests that Ethicon and Johnson & Johnson did that showed that the TVT mesh was markedly or moderately cytotoxic?

A. Which ones are you talking about?

Q. First of all, are you aware --

A. Yes.
Q. -- that there have been four separate tests?
A. Yes. In the '90s, I don't really place too much value on those based upon the current body of evidence which says that it is not cytotoxic.
Q. Are you aware of any cytotoxicity testing that Ethicon and Johnson & Johnson has done after the launch of the TVT mesh in the United States specifically with regard to cytotoxicity?
A. I'm sure I've read a couple of those as well.

Q. You believe you have seen cytotoxicity tests done on the TVT mesh after 1998?
A. I'm trying to think.
Q. I'd sure like to see them if they are out there.
A. You know, it's not jumping out right this second. Everything is kind of meshing in my head.
Q. I'm talking specifically about cytotoxicity.
A. I understand. Everything is kind of getting mixed up in my head as we're speaking --
Q. And you understand, from your review of the records, that one of the industry standard ways to check for cytotoxicity that's required is an ISO illusion test; right?
A. I mean, I think that was in one of the articles, yes.
Q. Okay. And are you aware of any instance

where Ethicon and Johnson & Johnson shared the results of its positive cytotoxicity tests with the TVT mesh with the FDA?

A. You know, again, those studies are kind of jumping away from me right now. I can look them up, but...

Q. Let me ask you this: Do you believe that those results should have been shared or disclosed

with the FDA?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: As of right now I'm kind of getting flustered in regards to what I read and those specific studies.

BY MR. FAES:

Q. Do you believe that the results of the cytotoxicity testing were the mesh tested cytotoxic on four separate occasions should be shared or disclosed to doctors who might choose to use the device?

A. Well, I kind of focus on the bulk of the data, and the bulk of the data, the bulk of the level 1 data. And as a clinician, cytotoxicity doesn't happen. It is not an issue in regards to how we use this mesh, in regards to how it's implanted and in regards to healing.

The mesh itself is actually really well tolerated in its appropriate use, and I don't feel as though it is cytotoxic. I think that most of the

time, with a very, very low erosion rate, a very low exposure rate, that it isn't cytotoxic. When you think about it, if a product is cytotoxic and 99 percent of the time there's no erosion, there is no reaction. It's inert. And to say that something is cytotoxic, I would expect 99 percent of the time for

there to be something going on, and there isn't.

Q. So you would agree with me that it's not the TVT mesh isn't well tolerated in the 2 to 3 percent of people that have an erosion or exposure; right?

A. No, I don't say that either. I'm not saying that that's cytotoxicity. I don't think that it's cytotoxicity that's causing the erosion. I think that is scarring and healing that is causing the erosion. I think that it's just sometimes it doesn't heal as well as you would like. I don't think that's a function of the mesh. I think that's a function of all implantable devices and anything you implant can have an erosion, can have an exposure. I don't think that it's cytotoxicity from the mesh that's contributing to -- when you -- like I said, again, when you look at the body of knowledge, how well it is tolerated, you kind of come to the conclusion that it's inert.

Q. What type of frequency and complications would you need to see from a mesh before you would start to consider that the material may be cytotoxic?

A. You know, that's a hypothetical question again. I don't have a pre-set number of what I would say or not say. All I know is that the exposure rate for the TVT is low, it's very low. It's inert. It is

well tolerated in the body. It does not cause cytotoxicity. When you look at complications from alternative procedures, things like pubovaginal slings and Burch procedures, there's way more complications with those.

Q. So you would agree with me that you can't articulate any objective standards for the type and frequency of complications that you would need to see from a mesh before you would start to consider that it's cytotoxic; right?

MR. KOOPMANN: Object to form.

Go ahead.

THE WITNESS: In regards to -- again, it's a hypothetical situation that I'm kind of like scratching my head about because I don't think this is a cytotoxic agent.

So if you are saying, okay, this non cytotoxic agents, how many erosions, what percentage of erosions would you have to see in order to say it's cytotoxic, you know, I don't know, because I have no idea what a cytotoxic substance would do in the vagina, because this isn't cytotoxic.

BY MR. FAES:

Q. So what objective standard are you applying for your opinion in a the TVT mesh is not cytotoxic?

A. I'm applying the medical societies, I'm applying the literature that's out there that repeatedly over and over says there's no cytotoxicity, that this is well tolerated in the vagina, that it's compatible with its intended use.

Q. So what would you need to see in order for you to reconsider your position that the mesh is cytotoxic?

A. I don't know. I don't have an answer to that question because it's what I would think ask an obscure hypothetical situation.

Q. You stated that you believe that the erosion rate for the TVT products is low. Is that accurate?

A. That is correct.

Q. Do you have an opinion that you intend to offer in this case as to what you believe the erosion rate is for the TVT retropubic?

A. I think I quoted right around under 2 percent.

Q. So you believe it's under 2 percent?

A. Yes.

Q. Is your answer the same with regard to the TVT-O?

A. Yes.

Q. The same with regard to the Abbrevo?

A. Yes.
Q. Same with regard to the Exact?
A. Yes.
Q. Would you agree with me that your opinion that the erosion rate is low and is less than 2 percent is part of the reason for your conclusion that the TVT devices are safe?
A. That is one specific complication regarding the TVT and I think that is a low, easily fixable, low severity complication. When you talk about complications, there is a range of complications and a mesh exposure I do think is a low severity complication that's easily fixable.
Q. What mesh erosion percentage would you need to see in the TVT family of products before you would start to reconsider your position that the TVT devices are safe?
MR. KOOPMANN: Object to form.
THE WITNESS: You know, I don't have a pre-set number of what I would do, but when I look at alternative treatments out there, you look at a Burch procedure, you look at the pubovaginal slings which have significantly higher erosion or significantly higher complication rates associated with its use and then you think about the benefit that women have from

this, I kind of focus on the 98, 99 percent of women that are now able to live their lives in a better way.

I look at the benefit and at their quality of life has significantly improved because they are not leaking, they are able to enjoy life as they should without having to worry about stress incontinence. The quality of life associated with chronic stress urinary incontinence is not as good if left untreated.

MR. KOOPMANN: You've gone six hours in.

MR. FAES: I told you I would wrap up within 20 minutes of that, so I'm almost done.

Q. Would you agree with me, then, that you don't have any objective quantifiable standard with regard to erosion rates before you would agree to consider your position that the TVT devices are safe?

A. I don't have a pre-set number in mind.

Q. Do you believe that the TVT mesh can shrink or contract?

A. Hold on one second. I'm trying to look at --

(Document review.)

With scarring, there can be some scarring associated with pulling things back in, but I don't think the device itself is shrinking with any sort of clinical significance.

Q. Would you agree with me that there could be

shrinkage or contraction of the tissue surrounding the mesh?

A. I think that there can be, as with scarring with any procedure, you can have some tightening of the connective tissue along the scar. You can also have some loosening as well.

Q. And you would agree with me that that shrinkage or contraction in the case of a TVT can potentially cause urinary retention after placement; right?

A. I do not. I don't think that the TVT shrinks to a point where -- I don't think the TVT shrinks and if there's scarring or increased resistance at the lower portion of the bladder, I don't think that that's a function of the TVT shrinking.

Q. So you've never seen that recorded in the medical literature, that a sling can tighten up after the postoperative period and cause urinary retention?

A. I don't think that the sling is what's tightening. I think that there might be scarring, there might be something, you know, change in the anatomy of the vaginal area that can contribute, but if it is, it's a rare event, and in regards to proper -- if the sling is properly tensioned, it should not result in long-term urinary retention.

Johnson & Johnson where medical directors from Ethicon apply a -- state that the mesh -- the polypropylene mesh can shrink up to 30 percent as a rule of thumb?

A. You know, I have seen documents that talk about shrinking up to 30 percent. I have not seen that in clinical practice. I don't think that the mesh shrinks 30 percent.

Q. So you disagree with that statement?

A. I do.

Q. So that's another instance where you feel that Ethicon's medical directors who are in charge of the TVT are just wrong; right?

A. I do, yes.

Q. Are you aware of any reports in the peer-reviewed medical literature that support that the mesh can contract up to 30 percent?

A. The bulk of the data out there does say that over time that the sling does not contract to a point where it's clinically relevant.

Q. But you would agree with me that there are some reports in the peer-reviewed medical literature of that occurring; right?

A. You know, nothing is jumping out that I've read offhand, and I'm not exactly sure what article

you're talking about right now.

Q. I'm just asking simply, as you sit here today, are you aware of any articles or reports in the

peer-reviewed medical literature that support the position that polypropylene mesh can shrink or contract up to 30 percent following placement?

A. There may be some articles out there, but when I focus on my background, I focus on the quality journals, the quality articles, the position statements from our medical societies, and those position statements do say that over time, even with long-term follow-up, that these slings don't -- it's not clinically relevant in regards to shrinking.

Q. So to the degree that those reports exist, you disregard those reports; right?

MR. KOOPMANN: Object to form.

THE WITNESS: You know, I don't put too much weight on those. What I do is I put more weight on the position statements of the societies, what the vast body of knowledge says, which is that it is not clinically relevant, and that's the -- where I put more weight on.

BY MR. FAES:

Q. Would you agree with me that excessive shrinkage or contraction of the tissue surrounding the

mesh is a potential adverse reaction of the TVT?

A. I do not think that's the case.

Q. Okay. Do you know whether that is a potential adverse reaction that is warned of in the IFUs of Ethicon's other Prolene mesh products?

MR. KOOPMANN: Objection to foundation.

THE WITNESS: You know, I haven't looked at their other IFUs, and that might be the case.

BY MR. FAES:

Q. Have you ever reviewed the IFU or instructions for use for the Gynemesh PS product?

A. Gynemesh PS, you know, if I have, it was a long time ago, but I have not recently.

Q. Are you aware that the Gynemesh PS product is made from the same Prolene polypropylene material as the TVT-Secur?

A. I believe it is.

Q. Okay. Do you believe that there's anything special or different about that mesh to where the adverse reactions for that mesh would be different from the potential adverse reactions of the TVT mesh?

MR. KOOPMANN: Object to form, foundation. He's not offered as a Gynemesh PS expert.

Go ahead.

THE WITNESS: Again, I'm not very familiar

with the Gynemesh PS.

BY MR. FAES:

Q. So is it fair to say that you don't know one way or the other whether or not there's anything different or special about the TVT mesh to where it wouldn't have the same potential adverse reactions as the Gynemesh PS mesh?

A. I don't know very much about the Gynemesh PS mesh, and because I can't -- don't feel I can comment on that when comparing something that I know to something that I don't know.

Q. As you sit here today, do you feel there's any corrections or changes that you need to make to your expert report marked as Exhibit Number 2 in front of you?

A. I think it's pretty good as it stands.

Q. Exhibit Number 5, which is your supplemental general materials list, does that contain a list of all the materials that you have reviewed and relied upon in offering your opinions today?

A. It's not -- I mean, the stuff that I've reviewed has been throughout my entire career in regards to training and in regards to position, so I wouldn't say that this is a complete list. I think that this is a really good start, because there's a

lot of material here. However, I've been reviewing stuff since I started training and getting educated on --

Q. Well, other than some peer-reviewed medical literature that may not be reflected on this list, is there anything else that you have reviewed and relied on that isn't reflected on your supplemental materials list marked as Exhibit 5?

A. Again, I think you are asking is this all

that I've used in order to prepare for today, and the answer is no, I've used my entire career, my mentors, my going to meetings, reading journals, and what's on here is an excellent, comprehensive kind of material, but it's not the only thing that was used.

Q. Okay. You understand this is my one opportunity to know what everything that you have reviewed and relied upon in issuing your opinions in your expert report; right?

A. I do, but it's difficult for me to say hey, when I was in fellowship I got a lecture on this or hey, somebody taught me how to tension a sling this way or, hey -- you know, so it's not just this. It's my entire career I kind of base it on. I can't provide everything that I've done in the past 12, 13 years of my career after training in addition to

the 12 years of training that have gone into providing you -- but I think it's a great place to start. I think it's a great comprehensive source of materials if you are looking for what I'm basing my opinions on, but it's also based on my entire career.

Q. Other than your entire career, are there any specific materials that you have reviewed and relied on in offering your opinions in this case that you can think of as you sit here today?

A. Again, like my prior answers, nothing jumps to mind.

MR. FAES: I'm trying to get him out of here, and he fights me on the non controversial stuff.

THE WITNESS: I'm not trying to fight you.

MR. FAES: Doctor, I don't think I have any further questions for you at this time. I may have some follow-up following any questioning by Mr. Koopmann.

EXAMINATION

BY MR. KOOPMANN:

Q. Dr. Wasserman, much earlier today there was some testimony about your reliance on high quality evidence versus other evidence. Do you generally

recall that discussion?

A. Yes.

Q. And there was some discussion about the extent to which you relied or reviewed on internal company documents and corporate witness depositions. Do you recall that generally?

A. Yes.

Q. When you were asked about quote-unquote high-quality evidence, do you mean quality in terms of its scientific value among surgeons vis-à-vis other types of scientific evidence?

MR. FAES: Object to form.

THE WITNESS: What do you mean by that?

BY MR. KOOPMANN:

Q. When you were asked about high-quality evidence or, quote-unquote, high-quality evidence, do you mean quality in terms of its scientific value among surgeons?

MR. FAES: Objection.

THE WITNESS: Yes, I do. How it relates to our clinical practice, yes.

BY MR. KOOPMANN:

Q. And I'm paraphrasing, but I think you indicated earlier that you didn't consider the company witness deposition testimony or internal documents to

be, quote-unquote, high-quality evidence. Do you recall that?

MR. FAES: Objection.

THE WITNESS: High-quality yes.

BY MR. KOOPMANN:

Q. Is level 1 evidence at the top of the pyramid of scientific evidence?

MR. FAES: Objection.

THE WITNESS: Yes, it is.

BY MR. KOOPMANN:

Q. Where do opinions of individuals fall on the pyramid of scientific evidence?

MR. FAES: Objection.

THE WITNESS: It's pretty low.

BY MR. KOOPMANN:

Q. And does that change if the person offering the opinion is the chief safety officer at a company?

MR. FAES: Objection.

THE WITNESS: Yes, it does not change at all. It doesn't matter who -- what position they take. I think I talked about this earlier. It doesn't matter their position or it's just one person's opinion.

BY MR. KOOPMANN:

Q. Were you disparaging the individuals being referenced or the e-mails that were being referenced

earlier, the authors of the e-mails or is it more about the general type of information that those things represent?

MR. FAES: Objection.

THE WITNESS: I wasn't disparaging them at all. I mean, I think that those are their opinions and they put their opinions out there, and I think my opinions are different you.

BY MR. KOOPMANN:

Q. Are case reports known in medicine as being merely hypothesis generating?

MR. FAES: Objection.

THE WITNESS: Mostly, yes. Case reports are not what defines how we go about care.

BY MR. KOOPMANN:

Q. Does the medical literature that you have relied on in forming your opinions regarding the

midurethral slings that are referenced in your report, does that take into account the different safety profiles of the TVT, TVT-O, TVT Abbrevo, and TVT Exact?

MR. FAES: Objection.

THE WITNESS: Yes, it does.

BY MR. KOOPMANN:

Q. The Ford Cochran review that you mentioned

earlier from 2017 and that you have cited in your report, that says quote Type I mesh has the highest biocompatibility with the least propensity for infection; is that correct?

MR. FAES: Objection.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q. And is that one of the documents that you relied upon in forming your opinions?

A. Yes, it is.

Q. And that Ford Cochran review also says, "Microporous meshes (pore size in excess of 75 microns) easily allow microphages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores. Thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection (Amid 1997)." Is that correct?

MR. FAES: Objection.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q. Is that one of the bases -- well, does that support your opinion that the TVT-O, TVT Abbrevo and TVT Exact meshes are macroporous meshes?

MR. FAES: Objection.

THE WITNESS: Yes, they are.

BY MR. KOOPMANN:

Q. And that supports that?

A. Yes, it does.

Q. Do you do active research regarding midurethral slings in the form of reading literature that comes out about midurethral slings?

MR. FAES: Objection.

THE WITNESS: I do.

BY MR. KOOPMANN:

Q. Is it fair to say that, as a surgeon who has been implanting midurethral slings for more than a decade, you know what surgeons need to know to use midurethral slings like the TVT, TVT Abbrevo, TVT-O and TVT Exact?

MR. FAES: Objection.

THE WITNESS: Yes, I do.

BY MR. KOOPMANN:

Q. Have you evaluated the design of the various midurethral slings that you have used over the course of your career, whether made by Ethicon or some other manufacturers?

MR. FAES: Objection.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q. And have you read the medical literature

regarding the use of the TVT family of slings and other manufacturers of midurethral slings?

MR. FAES: Objection.

THE WITNESS: Yes, I have.

BY MR. KOOPMANN:

Q. Are you confident of the equivalent complication rates between laser-cut mesh and mechanically-cut mesh slings in the TVT family of slings in your practice, even though you haven't done a formal analysis of those complication rates?

MR. FAES: Objection.

THE WITNESS: Yes, I have.

BY MR. KOOPMANN:

Q. Why?

A. Because they are equivalent. There's no difference between those two. When you look at the body of literature, look at what's been published, there's no clinical difference between those two.

Q. You were asked some questions earlier this afternoon about transvaginal mesh kits for pelvic organ prolapse treatment and why some products were removed from the market. Do you recall those questions generally?

MR. FAES: Objection.

THE WITNESS: Generally, yes.

BY MR. KOOPMANN:

Q. Do you have any knowledge regarding the reason that Ethicon's pelvic organ prolapse mesh kits were decommercialized?

MR. FAES: Objection.

THE WITNESS: I don't.

BY MR. KOOPMANN:

Q. One of the papers that you -- strike that.

One of the articles that you read in the course of forming your opinions in this case is an article by Pamela Wiley 2008 tensile properties of five commonly used midurethral slings relative to the TVT; is that right?

A. That's the University of Pittsburgh study, yes.

Q. And in that study, do you recall seeing a table that listed the weights in grams per meter squared of various manufacturers' mesh products?

MR. FAES: Object to form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q. And do you recall that the Gynecare mesh was listed as being 100 grams per meter squared in that study?

MR. FAES: Object to form.

THE WITNESS: It was.
BY MR. KOOPMANN:
Q. And the AMS mesh and the Caldera mesh were both listed as higher weights than the TVT mesh?
MR. FAES: Object to form.
THE WITNESS: Yes. Earlier I was trying to recall those numbers, but yes, that's where it same from.
BY MR. KOOPMANN:
Q. You were asked some questions earlier about whether you were aware of studies that tracked long-term pain or dyspareunia after the various sling procedures that you've written about in your expert report. Do you recall that questioning generally?
A. Yes, and I was trying to recall which of those articles it would apply to.
Q. Do you recall reading a systematic review and meta-analysis by Dr. Tommaselli from 2015?
A. Yes.
Q. And that was titled medium-term and long-term outcomes following placement of midurethral slings following stress urinary incontinence systematic review and meta-analysis; is that right?
A. Yes. That was the 2015?
Q. Yes.

A. Yes.
Q. One of the things that Dr. Tommaselli noted in that study is that persistent or chronic pain, i.e., pain persisting beyond the perioperative period or reported at the last follow-up visit, was reported by 13 patients for retropubic midurethral slings and 30 patients for transobturator midurethral slings. Is that correct?
MR. FAES: Object to form.
THE WITNESS: That is correct. I think it was like 3,000. It was a lot of patients.
BY MR. KOOPMANN:
Q. There were 3,974 retropubic and --
A. 2,400-something --
Q. Yes, of obturator; right?
A. Yes.
Q. Is that one of the studies -- well, do you think as a systematic review of medium and long-term studies that that study speaks to the rate of pain and dyspareunia -- chronic pain and dyspareunia?
A. Yes.
MR. FAES: Object to form.
BY MR. KOOPMANN:
Q. The Ford Cochran review looked at short-term, medium-term and long-term studies; correct?

MR. FAES: Object to form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q. And the Ford Cochran review indicated that at 24-month follow-up, rates of superficial and deep dyspareunia were low with no difference between the groups, meaning the transobturator and retropubic group. Is that right?
MR. FAES: Object to form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q. And does that study support the idea that the rates of chronic pain and dyspareunia with midurethral slings like those referenced in your expert report are low?
MR. FAES: Object to form. Leading.
THE WITNESS: Correct, it is low.
BY MR. KOOPMANN:
Q. And the Shimp study that's been referenced a couple of times today, that was a systematic review and meta-analysis; is that right?
A. Correct.
Q. And that study looked at randomized controlled trials with a minimum of 12 months of follow-up; correct?

A. Yes.
Q. And some of the studies referenced in Shimp

were long-term follow-up studies; correct?
MR. FAES: Object to form. Leading.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q. And the Shimp study reported on the rate of dyspareunia following retropubic midurethral sling procedures like the TVT and TVT Exact and transobturator midurethral procedures like the TVT-O and TVT Abbrevo; is that correct?
MR. FAES: Object to form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q. And it listed a zero percent rate of prune for the retropubic slings; is that right?
MR. FAES: Objection.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q. And 0.16 percent rate with transobturator slings; correct?
MR. FAES: Objection.
THE WITNESS: Correct.
BY MR. KOOPMANN:
Q. The Shimp study included a table that showed

the rates of complications with the Burch procedure, transobturator midurethral sling procedures, retropubic midurethral sling procedures, mini-sling procedures, and pubovaginal sling procedures; is that

right?

MR. FAES: Object to form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q. And Shimp noted that this type of surgery, meaning a midurethral sling surgery has evolved to also include options of obturator passage and smaller single-incision synthetic slings; e.g., mini-slings?

MR. FAES: Objection. Leading.

BY MR. KOOPMANN:

Q. Do you remember that?

A. Yes.

Q. So Shimp defines mini-slings as single-incision synthetic slings?

MR. FAES: Objection. Form.

THE WITNESS: That's kind of what I was alluding to before.

BY MR. KOOPMANN:

Q. In the medical literature you've reviewed regarding -- well, strike that.

When you read a medical -- a piece of medical

literature regarding mini-slings, do you consider that to include the TVT Abbrevo?

MR. FAES: Object to form.

THE WITNESS: I do not. I tried to make that clear earlier.

BY MR. KOOPMANN:

Q. Are complaints that are made to a medical device company from individual surgeons anecdotal evidence?

A. Yes.

MR. FAES: Object to form.

BY MR. KOOPMANN:

Q. How valuable is anecdotal evidence in the grand scheme of scientific evidence?

MR. FAES: Object to form.

THE WITNESS: It is not very valuable. It is not high quality. It's not very valuable. It's low.

MR. KOOPMANN: Those are all the questions I have for you, Doctor. Thanks.

FURTHER EXAMINATION

BY MR. FAES:

Q. Few follow-up questions for us. You were asked some questions about the testimony of Ethicon's

medical directors, and I think you stated that -- defined opinions of individuals to be of low value; right?

A. Yes.

Q. Does that mean that your opinions as an individual are also of low value?

A. These are my opinions.

Q. We talked about --

A. They are valuable to me.
Q. Okay. We talked earlier about how you believe that someone who offers a Burch procedure as their primary procedure for stress urinary incontinence, you consider that person to be an outlier; right?
A. I tried to convey that most people that are doing anti incontinence procedures in any sort of volume will use a midurethral sling.
Q. Okay. Does that make you an outlier if you disagree with multiple opinions of Ethicon's own medical directors about the TVT product?
MR. KOOPMANN: Object to form.
THE WITNESS: Say that again.
BY MR. FAES:
Q. Do you believe it makes you an outlier if you disagree with multiple opinions of Ethicon's own

medical directors who were responsible for the safety of the TVT products?
A. I don't think those two situations are comparable. I think that I'm talking about what most people are doing for a procedure, and you're talking about that my feeling that the opinions given in the testimony are not of high value. That's totally different. It's apples to oranges.
Q. So you don't feel like the fact that you disagree with multiple opinions and statements by

Ethicon's own medical directors and now you've been hired by Ethicon and disagree with multiple numbers of those opinions, that that makes you an outlier in any way?

A. I don't think I'm an outlier, but you would have to ask other people. You are asking me if I feel as though my opinion that their opinions that I disagree with them that it makes me an outlier. You know, I don't know the answer to that. But I think that I have an opinion, they have an opinion, and if my opinion differs from their opinion, if everybody else says that their opinion is right, does that make me an outlier? I don't know. I haven't talked to everybody in regards to what their opinion is on their opinion.

Q. You would agree with me that if you are going to implant a medical device in a patient, you want to select the best possible medical device for that patient; right?

A. You want to offer the best possible surgery that's the safest and most effective.

Q. And right now you don't offer any of the TVT products to your patients for the treatment of stress urinary incontinence; right?

A. That is has to do with contractual obligations in regards to the hospitals in which I work. I do think that the Caldera sling is equivalent

to the TVT.

Q. Okay. So you would agree, then, that the TVT isn't the best surgical option for the treatment of stress urinary incontinence, that Caldera is equivalent; right?

A. Absolutely not.

Q. What do you believe is the best surgical treatment for stress urinary incontinence?

A. A midurethral sling.

Q. Any midurethral sling?

A. Any full-length -- right now in my hands, a full-length midurethral sling, yes.

Q. So it's your opinion that any midurethral

sling is the best surgical option to offer a patient; it doesn't matter if it's Ethicon, Caldera, Boston Scientific; right?

A. In regards to midurethral slings that are currently available, I think that there's equivalence across the board on the retropubic and the transvaginal obturators, those full-length slings, which in my personal hands -- a lot of it also is surgeon's preference too. So in my hands, in my surgical experience and what I do a lot of, in my hands, any retropubic sling is equally efficacious and equally safe.

Q. When you offer the Caldera slings to your patients, you tell them that that's the best surgical

option to treat their stress urinary incontinence; right?

A. I don't present it as a Caldera. I don't present it with brands. I present it with midurethral slings. I don't say this brand is better.

Q. Okay.

A. It would be the equivalent of saying Nike's are better than Rebocks and you go to a race and someone has got Nikes, somebody has Rebocks, it's the same basic product as long as you run really fast.

Q. So in your opinion they are all essentially

the same; is that right?

MR. KOOPMANN: Object to form.

THE WITNESS: I don't think they are the same. I think their efficacy and their safety profiles are the same.

BY MR. FAES:

Q. You were asked some questions about the Molalli (phonetic) study and the weights that were reported in that study?

A. Yes.

Q. Do you have an understanding that the mow alley study didn't do any actual study of measurement, independent study or measurement of the weights or pore size of the mesh, they were just recording the weights and mesh size as reported to Dr. Mow alley in the study participants by the manufacturers?

A. I believe that's true.

MR. FAES: Okay. So there was no independent verification of the weights or pore size by Dr. Monthly alley in that study; right.

A. I do not believe that she looked at the pore sizes or the weights. However, there's nothing to make me think that the reported weights or pore sizes were incorrect.

BY MR. FAES:

Q. You were asked some questions about the Tommaselli study. Do you remember that?

A. Yes.

Q. And that is a meta-analysis. It is not a randomized controlled trial; right?

A. That's the Cochran one, I believe?

Q. Ford is the Cochran. Tommaselli is the metanalysis. I'm going to get to Ford.

A. Okay.

Q. My questions earlier were specifically about how many randomized controlled trials with a primary endpoint of safety that were not about meta-analysis; right?

A. Hold on. I'm turning to the page. I didn't actually hear you. Say that again.

Q. My questions that I asked you earlier were not about meta-analyses; they were about randomized

controlled trials with a primary endpoint of safety; right?

A. I believe they were.

Q. And Tommaselli is not a randomized controlled trial with a primary endpoint of safety, it's a meta-analysis; right?

A. That's correct.

Q. And the Ford Cochran review is not a randomized controlled trial with a primary endpoint of safety. It's a meta-analysis. Right?

A. Yes. And meta-analyses are very good for trying to figure out what's going on and how we base our opinions.

Q. And the Shimp study, that is also a meta-analysis and not a randomized controlled trial with a primary endpoint of safety; right?

A. Correct, and again, I place high value on meta-analyses.

MR. FAES: That's all the further questions I have.

MR. KOOPMANN: I'd like to have the witness read and sign, and just for the record, just so we're clear, USB drive, Deposition Exhibit 9, you want to retain that, Andy?

MR. FAES: Yes. Unless you want me to send it to her for some reason. I'm just going to put it on the cloud and it's going to sit in my desk drawer

with 500 other drives that I've gotten from defense lawyers over the past five years.

MR. KOOPMANN: I think you should save this so we have some record.

MR. FAES: Yeah. It will be in the drawer

with all the other ones and also be in the cloud because we all live forever on the cloud.

MR. KOOPMANN: You might want to write Wasserman on there.

MR. FAES: That's a good idea.

MR. KOOPMANN: There is a password for it that I'll tell you off the record.

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